post-hospital extended care services, and physicians'services).

Provider has the same meaning as specified under § 400.202 of this chapter.

Qualified chain provider means a chain provider comprised of—

(1) 10 or more eligible providers collectively totaling 500 or more certified beds; or

(2) 5 or more eligible providers collectively totaling 300 or more certified beds, with eligible providers in 3 or more contiguous States.

Supplier has the same meaning as specified in § 400.202 of this chapter.

(b) *Assignment of providers to MACs.* (1) Providers enroll with and receive Medicare payment and other Medicare services from the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the provider's covered services for the geographic locale in which the provider is physically located.

(2) Qualified chain providers may request and receive an exception from the requirement of paragraph (b)(1) of this section from CMS. Upon CMS'approval, a qualified chain provider may enroll with and bill on behalf of the eligible providers under its common ownership or common control to the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the eligible providers'covered services for the geographic locale in which the qualified chain provider's home office is physically located.

(3) As MAC contractors become available, qualified chain providers, granted approval by CMS to enroll with and bill a single intermediary on behalf of their eligible member providers prior to October 1, 2005, will be assigned at an appropriate time to the MAC contracted by CMS to administer claims for the applicable Medicare benefit category for the geographic locale in which the chain provider's home office is physically located. The qualified chain provider will not need to request an exception to the requirement of paragraph (b)(1) of this section in order for this assignment to take effect.

(4) CMS may grant an exception to the requirement of paragraph (b)(1) of this section to eligible providers that are not under the common ownership or common control of a qualified chain provider, as well as ineligible providers, only if CMS finds the exception will support the implementation of MACs or will serve some other compelling interest of the Medicare program.

(c) *Assignment of suppliers to MACs.* (1) Suppliers, including physicians and other practitioners, but excluding suppliers of DMEPOS, enroll with and receive Medicare payment and other Medicare services from the MAC contracted by CMS to administer claims for the Medicare benefit category applicable to the supplier's covered services for the geographic locale in which the supplier furnished such services.

(2) Suppliers of DMEPOS receive Medicare payment and other Medicare services from the MAC assigned to administer claims for DMEPOS for the regional area in which the beneficiary receiving the DMEPOS resides. The terms of §§ 421.210 and 421.212 continue to apply to suppliers of DMEPOS.

(3) CMS may allow a group of ESRD suppliers under common ownership and common control to enroll with the MAC contracted by CMS to administer ESRD claims for the geographic locale in which the group's home office is located only if—

(i) The group of ESRD suppliers requests such privileges; and

(ii) CMS finds the exception will support the implementation of MACs or will serve some other compelling interest of the Medicare program.

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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:

(1) The following provisions of the Act:

(i) 1106—Disclosure of information in possession of agency.

(ii) 1128J(d)—Reporting and Returning of Overpayments.

(iii) 1851—Eligibility, election, and enrollment.

(iv) 1852—Benefits and beneficiary protections.

(v) 1853—Payments to Medicare Advantage (MA) organizations.

(vi) 1854—Premiums.

(vii) 1855—Organization, licensure, and solvency of MA organizations.

(viii) 1856—Standards.

(ix) 1857—Contract requirements.

(x) 1858—Special rules for MA Regional Plans.

(xi) 1859—Definitions; enrollment restriction for certain MA plans.

(2) 8 U.S.C. 1611—Aliens who are not qualified aliens ineligible for Federal public benefits.

(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; 80 FR 7958, Feb. 12, 2015; 81 FR 80556, Nov. 15, 2016]

§ 422.2 Definitions.

As used in this part—

Aligned enrollment refers to the enrollment in a dual eligible special needs plan of full-benefit dual eligible individuals whose Medicaid benefits are covered under a Medicaid managed care organization contract under section 1903(m) of the Act between the applicable State and: the dual eligible special needs plan's (D–SNP's) MA organization, the D–SNP's parent organization, or another entity that is owned and controlled by the D–SNP's parent organization. When State policy limits a D–SNP's membership to individuals with aligned enrollment, this condition is referred to as exclusively aligned enrollment.

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.

Attestation process means a CMS-developed RADV audit-related process that is part of the medical record review process that enables MA organizations undergoing RADV audit to submit CMS-generated attestations for eligible medical records with missing or illegible signatures or credentials. The purpose of the CMS-generated attestations is to cure signature and credential issues. CMS-generated attestations do not provide an opportunity for a provider or supplier to replace a medical record or for a provider or supplier to attest that a beneficiary has the medical condition

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.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MA organization (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.

Dual eligible special needs plan or D–SNP means a specialized MA plan for special needs individuals who are entitled to medical assistance under a State plan under title XIX of the Act that—

(1) Coordinates the delivery of Medicare and Medicaid services for individuals who are eligible for such services;

(2) May provide coverage of Medicaid services, including long-term services and supports and behavioral health services for individuals eligible for such services;

(3) Has a contract with the State Medicaid agency consistent with § 422.107 that meets the minimum requirements in paragraph (c) of such section; and

(4) Beginning January 1, 2021, satisfies one or more of the following criteria for the integration of Medicare and Medicaid benefits:

(i) Meets the additional requirement specified in § 422.107(d) in its contract with the State Medicaid agency.

(ii) Is a highly integrated dual eligible special needs plan.

(iii) Is a fully integrated dual eligible special needs plan.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with an MA organization or applicant to provide administrative services or health care services for a Medicare eligible individual under the MA program.

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

Fully integrated dual eligible special needs plan means a dual eligible special needs plan—

(1) That provides dual eligible individuals access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid managed care organization contract under section 1903(m) of the Act with the applicable State;

(2) Whose capitated contract with the State Medicaid agency requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a fully integrated dual eligible special needs plan (FIDE SNP) in the State, except as approved by CMS under § 422.107(g) and (h):

(i) Primary care and acute care, and for plan year 2025 and subsequent years including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries;

(ii) Long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the plan year;

(iii) For plan year 2025 and subsequent years, behavioral health services;

(iv) For plan year 2025 and subsequent years, home health services as defined in § 440.70 of this chapter; and

(v) For plan year 2025 and subsequent years, medical supplies, equipment, and appliances, as described in § 440.70(b)(3) of this chapter;

(3) That coordinates the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries;

(4) That employs policies and procedures approved by CMS and the State to coordinate or integrate beneficiary communication materials, enrollment, communications, grievance and appeals, and quality improvement;

(5) For plan year 2025 and subsequent years, that has exclusively aligned enrollment; and

(6) For plan year 2025 and subsequent years, whose capitated contract with the State Medicaid agency covers the entire service area for the dual eligible special needs plan.

Hierarchical condition categories (HCC) means disease groupings consisting of disease codes (currently ICD–9–CM codes) that predict average healthcare spending. HCCs represent the disease component of the enrollee risk score that are applied to MA payments.

Highly integrated dual eligible special needs plan means a dual eligible special needs plan offered by an MA organization that provides coverage of Medicaid benefits under a capitated contract that meets the following requirements—

(1) The capitated contract is between the State Medicaid agency and—

(i) The MA organization; or

(ii) The MA organization's parent organization, or another entity that is owned and controlled by its parent organization;

(2) The capitated contract requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a highly integrated dual eligible special needs plan (HIDE SNP) in the State, except as approved by CMS under § 422.107(g) or (h):

(i) Long-term services and supports, including community-based long-term services and supports and some days of coverage of nursing facility services during the plan year; or

(ii) Behavioral health services; and

(3) For plan year 2025 and subsequent years, the capitated contract covers the entire service area for the dual eligible special needs plan.

Institutionalized means, for the purposes of defining a special needs individual and for the open enrollment period for institutionalized individuals at § 422.62(a)(4), an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in one of the following long-term care facility settings:

(1) Skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare).

(2) Nursing facility (NF) as defined in section 1919 of the Act (Medicaid).

(3) Intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act.

(4) Psychiatric hospital or unit as defined in section 1861(f) of the Act.

(5) Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act.

(6) Long-term care hospital as defined in section 1886(d)(1)(B) of the Act.

(7) Hospital which has an agreement under section 1883 of the Act (a swing-bed hospital).

(8) Subject to CMS approval, a facility that is not listed in paragraphs (1) through (7) of this definition but meets both of the following:

(i) Furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and

(ii) Whose residents have similar needs and healthcare status as residents of one or more facilities listed in paragraphs (1) through (7) of this definition.

Institutionalized-equivalent means for the purpose of defining a special needs individual, an MA eligible individual who is living in the community but requires an institutional level of care. The determination that the individual requires an institutional level of care (LOC) must be made by—

(1) The use of a State assessment tool from the State in which the individual resides; and

(2) An assessment conducted by an impartial entity and having the requisite knowledge and experience to accurately identify whether the beneficiary meets the institutional LOC criteria. In States and territories that do not have an existing institutional level of care assessment tool, the individual must be assessed using the same methodology that State uses to determine institutional level of care for Medicaid nursing home eligibility.

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.

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

Point of service (POS) means a benefit option that an MA HMO plan can offer to its Medicare enrollees as a mandatory supplemental, or optional supplemental benefit. Under the POS benefit option, the HMO plan allows members the option of receiving specified services outside of the HMO plan's provider network. In return for this flexibility, members typically have higher cost-sharing requirements for services received and, when offered as a mandatory or optional supplemental benefit, may also be charged a premium for the POS benefit option.

Preclusion list means a CMS compiled list of individuals and entities that—

(1) Meet all of the following requirements:

(i) The individual or entity is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

(ii) The individual or entity is currently under a reenrollment bar under § 424.535(c).

(iii) CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph (1)(iii), CMS considers the following factors:

(A) The seriousness of the conduct underlying the individual's or entity's revocation.

(B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program.

(C) Any other evidence that CMS deems relevant to its determination; or

(2) Meet both of the following requirements:

(i) The individual or entity has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.

(ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph (2)(ii), CMS considers the following factors:

(A) The seriousness of the conduct involved.

(B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program; and

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The individual or entity, regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph (3) are—

(i) The severity of the offense;

(ii) When the offense occurred; and

(iii) Any other information that CMS deems relevant to its determination.

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.

RADV appeal process means an administrative process that enables MA organizations that have undergone RADV audit to appeal the Secretary's medical record review determinations and the Secretary's calculation of an MA organization's RADV payment error.

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.

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.

Risk adjustment data validation (RADV) audit means a payment audit of a MA organization administered by the Secretary that ensures the integrity and accuracy of risk adjustment payment data.

Senior housing facility plan means an MA coordinated care plan that—

(1) Restricts enrollment to individuals who reside in a continuing care retirement community as defined in § 422.133(b)(2);

(2) Provides primary care services onsite and has a ratio of accessible physicians to beneficiaries that CMS determines is adequate consistent with prevailing patterns of community health care referenced at § 422.112(a)(10);

(3) Provides transportation services for beneficiaries to specialty providers outside of the facility; and

(4) Was participating as of December 31, 2009 in a demonstration established by CMS for not less than 1 year.

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. Facilities in which individuals are incarcerated are not included in the service area of an MA plan. 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.

Severe or disabling chronic condition means for the purpose of defining a special needs individual, an MA eligible individual who has one or more co-morbid and medically complex chronic conditions that are substantially disabling or life-threatening, has a high risk of hospitalization or other significant adverse health outcomes, and requires specialized delivery systems across domains of care.

Special needs individual means an MA eligible individual who is institutionalized or institutionalized-equivalent, as those terms are defined in this section, 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 an MA coordinated care plan that exclusively enrolls special needs individuals as set forth in § 422.4(a)(1)(iv) and that 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 an 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.

Step therapy means a utilization management policy for coverage of drugs that begins medication for a medical condition with the most preferred or cost effective drug therapy and progresses to other drug therapies if medically necessary.

[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; 72 FR 68722, Dec. 5, 2007; 74 FR 1540, Jan. 12, 2009; 75 FR 19803, Apr. 15, 2010; 76 FR 21561, Apr. 15, 2011; 79 FR 29955, May 23, 2014; 83 FR 16722, Apr. 16, 2018; 84 FR 15827, Apr. 16, 2019; 84 FR 23879, May 23, 2019; 86 FR 6094, Jan. 19, 2021; 87 FR 27893, May 9, 2022]

§ 422.3 MA organizations' use of reinsurance.

(a) An MA organization may obtain insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee in either of the following ways—

(1) The MA organization must retain risk for at least the first $10,000 in costs per individual enrollee for providing basic benefits during a contract year; or

(2) If the MA organization uses insurance or makes other arrangements for sharing such costs proportionately on a per member per year first dollar basis, the MA organization must retain risk based on the following:

(i) The actuarially equivalent value of the retained risk is greater than or equal to the value of risk retained in paragraph (a)(1) of this section.

(ii) The MA organization makes a determination of actuarial equivalence based on reasonable actuarial methods. For example, a reasonable method for determining actuarial equivalence would be to equate the percentage of net claim costs that the MA organization would retain under paragraphs (a)(1) and (a)(2)(i) of this section.

(b) In evaluating compliance with section 1855(b) of the Act and with paragraph (a) of this section, CMS will consider a parent organization and any of its subsidiaries to be part of the MA organization.

(c) The type of payment arrangement used between an MA organization and contracting physicians, other health professionals or institutions for the financial risk specified in section 1855(b)(4) of the Act (that is, the financial risk on a prospective basis for the provision of basic benefit by those physicians or other health professionals or through those institutions) is not limited by paragraph (a) of this section.

[85 FR 33901, June 2, 2020]

§ 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 any of the following:

(A) Health maintenance organizations (HMOs);

(B) Provider-sponsored organizations (PSOs), subject to paragraph (a)(1)(vi) of this section.

(C) Regional or local preferred provider organizations (PPOs) as specified in paragraph (a)(1)(v) of this section.

(D) 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's SNP requirements and exclusively enrolls special needs individuals as defined by § 422.2 of this subpart. All MA plans wishing to offer a SNP will be required to be approved by the National Commission on Quality Assurance (NCQA) effective January 1, 2012. This approval process applies to existing SNPs as well as new SNPs joining the program. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance.

(v) A PPO plan is a plan that—

(A) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(B) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers;

(C) 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; and

(D) Does not permit prior notification for out-of-network services—that is, a reduction in the plan's standard cost-sharing levels when the out-of-network provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PPO plan prior to receiving plan-covered services from an out-of-network provider.

(vi) In accordance with § 422.370, CMS does not waive the State licensure requirement for organizations seeking to offer a PSO.

(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);

(B) Does not permit prior notification—that is, a reduction in the plan's standard cost-sharing levels when the

provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the MSA plan prior to receiving plan-covered services from a provider; and

(C) 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) Subject to paragraphs (a)(3)(ii)(A) and (B) of this section, does not vary the rates for a provider based on the utilization of that provider's services; and

(A) May vary the rates for a provider based on the specialty of the provider, the location of the provider, or other factors related to the provider that are not related to utilization and do not violate § 422.205 of this part.

(B) May increase the rates for a provider based on increased utilization of specified preventive or screening services.

(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.

(iv) Does not permit prior notification—that is, a reduction in the plan's standard cost-sharing levels when the provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PFFS plan prior to receiving plan-covered services from a provider.

(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; 73 FR 54248, Sept. 18, 2008; 74 FR 1541, Jan. 12, 2009; 75 FR 19804, Apr. 15, 2010; 76 FR 21561, Apr. 15, 2011]

§ 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 meets all of the following:;

(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) For coverage before January 1, 2021, 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.

(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.

(7) Is a United States citizen or is lawfully present in the United States as determined in 8 CFR 1.3.

(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; 80 FR 7958, Feb. 12, 2015; 85 FR 33901, June 2, 2020]

§ 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.* For plan years beginning before January 1, 2021, 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) *Establishing eligibility for enrollment.* A SNP must employ a process approved by CMS to verify the eligibility of each individual enrolling in the SNP.

[70 FR 4716, Jan. 28, 2005, as amended at 74 FR 1541, Jan. 12, 2009; 85 FR 33901, June 2, 2020]

§ 422.53 Eligibility to elect an MA plan for senior housing facility residents.

(a) *Basic eligibility requirements.* To be eligible to elect an MA senior housing facility plan, the individual must meet both of the following:

(1) Be a resident of an MA senior housing facility defined in § 422.2.

(2) Be eligible to elect an MA plan under § 422.50.

(b) *Restricting enrollment.* An MA senior housing facility plan must restrict enrollment to only those individuals who reside in a continuing care retirement community as defined at § 422.133(b)(2).

(c) *Establishing eligibility for enrollment.* An MA senior housing facility plan must verify the eligibility of each individual enrolling in its plan using a CMS approved process.

[76 FR 21561, Apr. 15, 2011]

§ 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 communication 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 communication 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; 83 FR 16722, Apr. 16, 2018]

§ 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) and (4) 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 § 422.2262. 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.

(g) *Passive enrollment by CMS*—(1) *Circumstances in which CMS may implement passive enrollment.* CMS may implement passive enrollment procedures in any of the following situations:

(i) Immediate terminations as provided in § 422.510(b)(2)(i)(B).

(ii) CMS determines that remaining enrolled in a plan poses potential harm to the members.

(iii) CMS determines, after consulting with the State Medicaid agency that contracts with the dual eligible special needs plan that is described in paragraph (g)(2)(i) of this section and meets the requirements of paragraph (g)(2) of this section, that the passive enrollment will promote integrated care and continuity of care for a full-benefit dual eligible beneficiary (as defined in § 423.772 of this chapter and entitled to Medicare Part A and enrolled in Part B under title XVIII) who is currently enrolled in an integrated dual eligible special needs plan.

(2) *MA plans that may receive passive enrollments.* CMS may implement passive enrollment described in paragraph (g)(1)(iii) of this section only into MA–PD plans that meet all the following requirements:

(i) Operate as a fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan.

(ii) Have substantially similar provider and facility networks and Medicare- and Medicaid-covered benefits as the plan (or plans) from which the beneficiaries are passively enrolled.

(iii) Have an overall quality rating from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252.

(iv) Not have any prohibition on new enrollment imposed by CMS.

(v) Have limits on premiums and cost-sharing appropriate to full-benefit dual eligible beneficiaries.

(vi) Have the operational capacity to passively enroll beneficiaries and agree to receive the enrollments.

(3) *Passive enrollment procedures.* Individuals will be considered to have elected the plan selected by CMS unless they—

(i) Decline the plan selected by CMS, in a form and manner determined by CMS, or

(ii) Request enrollment in another plan.

(4) *Beneficiary notification.* The MA organization that receives the passive enrollment must provide to the enrollee:

(i) In the case of a passive enrollment described in paragraphs (g)(1)(i) and (ii) of this section, a notice that describes the costs and benefits of the plan and the process for accessing care under the plan and clearly explains the beneficiary's ability to decline the enrollment or choose another plan. This notice must be provided to all potential passively-enrolled enrollees, in a form and manner determined by CMS, prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical).

(ii) In the case of a passive enrollment described in paragraph (g)(1)(iii) of this section, two notices that describe the costs and benefits of the plan and the process for accessing care under the plan and clearly explain the beneficiary's ability to decline the enrollment or choose another plan.

(A) The first notice described in paragraph (g)(4)(ii) of this section must be provided, in a form and manner determined by CMS, no fewer than 60 calendar days prior to the enrollment effective date.

(B) The second notice described in paragraph (g)(4)(ii) of this section must be provided, in a form and manner determined by CMS, no fewer than 30 days prior to the enrollment effective date.

(5) *Special election period.* In the case of a passive enrollment described in this paragraph, individuals will be provided with a special enrollment period described in at § 423.38(c)(10) of this chapter.

[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; 74 FR 1541, Jan. 12, 2009; 77 FR 22166, Apr. 12, 2012; 83 FR 16722, Apr. 16, 2018; 84 FR 15828, Apr. 16, 2019]

§ 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) For 2002 through 2010, except for 2006, the annual coordinated election period for the following calendar year is November 15 through December 31.

(ii) For 2006, the annual coordinated election period begins on November 15, 2005 and ends on May 15, 2006.

(iii) Beginning in 2011, the annual coordinated election period for the following calendar year is October 15 through December 7.

(iv) 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 period for individuals enrolled in MA*—(i) *For 2019 and subsequent years.* Except as provided in paragraphs (a)(3)(ii) and (iii) and (a)(4) of this section, an individual who is enrolled in an MA plan may make an election once during the first 3 months of the year to enroll in another MA plan or disenroll to obtain Original Medicare. An individual who chooses to exercise this election may also make a coordinating election to enroll in or disenroll from Part D, as specified in § 423.38(e) of this chapter.

(ii) *Newly eligible MA individual.* For 2019 and subsequent years, a newly MA eligible individual who is enrolled in a MA plan may 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 third month of the entitlement. An individual who chooses to exercise this election may also make a coordinating election to enroll in or disenroll from Part D, as specified in § 423.38(e) of this chapter.

(iii) *Single election limitation.* The limitation to one election or change in paragraphs (a)(3)(i) and (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.

(4) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to elect an MA plan and who is institutionalized, as defined in § 422.2, 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.

(5) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Through 2018, at any time from January 1 through February 14, an individual who is enrolled in an MA plan may elect Original Medicare once during this 45-day period. An individual who chooses to exercise this election may also make a coordinating election to enroll in a PDP as specified in § 423.38(d) of this chapter.

(b) *Special election periods (SEPs).* 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 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 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 communications as outlined in subpart V of this part.

(4) The individual is making an MA enrollment request into or out of an employer sponsored MA plan, is disenrolling from an MA plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan. This SEP is available to individuals who have (or are enrolling in) an employer or union sponsored MA plan and ends 2 months after the month the employer or union coverage of any type ends. The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

(5) The individual is enrolled in an MA plan offered by an MA organization that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with disclosure requirements at § 422.111(g), CMS may require the MA organization to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another MA plan or disenroll to original Medicare and enroll in a PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(6)(i) The individual is enrolled in a section 1876 cost contract that is not renewing its contract for the area in which the enrollee resides.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(7) The individual is disenrolling from an MA plan to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in an MA plan after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect an MA plan.

(ii) An individual who disenrolls from an MA plan has a SEP for 2 months after the effective date of MA disenrollment to elect a PACE plan.

(8) The individual terminated a Medigap policy upon enrolling for the first time in an MA plan and is still in a ''trial period'' and eligible for ''guaranteed issue'' of a Medigap policy, as outlined in section 1882(s)(3)(B)(v) of the Act.

(i) This SEP allows an eligible individual to make a one-time election to disenroll from his or her first MA plan to join original Medicare at any time of the year.

(ii) This SEP begins upon enrollment in the MA plan and ends after 12 months of enrollment or when the individual disenrolls from the MA plan, whichever is earlier.

(9) Until December 31, 2020, the individual became entitled to Medicare based on ESRD for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during his or her Initial Coverage Election Period (ICEP).

(i) The individual may prospectively elect an MA plan offered by an MA organization, provided—

(A) The individual was enrolled in a health plan offered by the same MA organization the month before their entitlement to Parts A and B;

(B) The individual developed ESRD while a member of that health plan; and

(C) The individual is still enrolled in that health plan.

(ii) This SEP begins the month the individual receives the notice of the Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received.

(10) The individual became entitled to Medicare for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during their initial coverage election period (ICEP). This SEP begins the month the individual receives the

notice of the retroactive Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received. The effective date would be the first of the month following the month in which the election is made but would not be earlier than the first day of the month in which the notice of the Medicare entitlement determination is received by the individual.

(11)(i) The individual enrolled in an MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the applicable special needs status.

(ii) This SEP begins the month the individual's special needs status changes and ends when the individual makes an enrollment request or 3 calendar months after the effective date of involuntary disenrollment from the SNP, whichever is earlier.

(12) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in an MA–PD plan.

(i) The individual may make one MA election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(13)(i) The individual has severe or disabling chronic conditions and is eligible to enroll into a Chronic Care SNP designed to serve individuals with those conditions. The SEP is for an enrollment election that is consistent with the individual's eligibility for a Chronic Care SNP. Individuals enrolled in a Chronic Care SNP who have a severe or disabling chronic condition which is not a focus of their current SNP are eligible for this SEP to request enrollment in a Chronic Care SNP that focuses on this other condition. Individuals who are found after enrollment not to have the qualifying condition necessary to be eligible for the Chronic Care SNP are eligible for a SEP to enroll in a different MA plan.

(ii) This SEP is available while the individual has the qualifying condition and ends upon enrollment in the Chronic Care SNP. This SEP begins when the MA organization notifies the individual of the lack of eligibility and extends through the end of that month and the following 2 calendar months. The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(14) The individual is enrolled in an MA–PD plan and requests to disenroll from that plan to enroll in or maintain other creditable prescription drug coverage.

(i) This SEP is available while the individual is enrolled in an MA–PD plan. The effective date of disenrollment from the MA plan is the first day of the month following the month a disenrollment request is received by the MA organization.

(ii) Permissible enrollment changes during this SEP are to disenroll from an MA–PD plan and elect original Medicare or to elect an MA-only plan, resulting in disenrollment from the MA–PD plan.

(15) The individual is requesting enrollment in an MA plan offered by an MA organization with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the MA plan was assigned a 5-star overall performance rating, beginning the December 8th before that contract year through November 30th of that contract year.

(16) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(i) This SEP begins the month the individual attains lawful presence status and ends the earlier of when the individual makes an enrollment election or 2 calendar months after the month the individual attains lawful presence status.

(ii) [Reserved]

(17) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973 within the same timeframe that the MA organization or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an enrollment election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) MA organizations may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of the requested materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(18) Individuals affected by an emergency or major disaster declared by a Federal, state or local government entity are eligible for a SEP to make a MA enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier, and ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later. The individual is eligible for this SEP provided the individual—

(i) (A) Resides, or resided at the start of the SEP eligibility period described in this paragraph (b)(18), in an area for which a federal, state or local government entity has declared an emergency or major disaster; or

(B) Does not reside in an affected area but relies on help making healthcare decisions from one or more individuals who reside in an affected area; and

(ii) Was eligible for another election period at the time of the SEP eligibility period described in this paragraph (b)(18); and

(iii) Did not make an election during that other election period due to the emergency or major disaster.

(19) The individual experiences an involuntary loss of creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable and excluding any loss or reduction of creditable coverage that is due to a failure to pay premiums.

(i) The individual is eligible to request enrollment in an MA–PD plan.

(ii) The SEP begins when the individual is notified of the loss of creditable coverage and ends 2 calendar months after the later of the loss (or reduction) or the individual's receipt of the notice.

(iii) The effective date of this SEP is the first of the month after the enrollment election is made or, at the individual's request, may be up to 3 months prospective.

(20) The individual was not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage. CMS determines eligibility for this SEP on a case-by-case basis, based on its determination that an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable.

(i) The individual is eligible for one enrollment in, or disenrollment from, an MA–PD plan.

(ii) This SEP begins the month of CMS' determination and continues for 2 additional calendar months following the determination.

(21) The individual's enrollment or non-enrollment in an MA–PD plan is erroneous due to an action, inaction, or error by a Federal employee.

(i) The individual is permitted enrollment in, or disenrollment from, the MA–PD plan, as determined by CMS.

(ii) This SEP begins the month of CMS approval of this SEP on the basis that the individual's enrollment was erroneous due to an action, inaction, or error by a Federal employee and continues for 2 additional calendar months following this approval.

(22) The individual is eligible for an additional Part D Initial Election Period, such as an individual currently entitled to Medicare due to a disability and who is attaining age 65.

(i) The individual is eligible to make an MA election to coordinate with the additional Part D Initial Election Period.

(ii) The SEP may be used to disenroll from an MA plan, with or without Part D benefits, to enroll in original Medicare, or to enroll in an MA plan that does not include Part D benefits, regardless of whether the individual uses the Part D Initial Election Period to enroll in a PDP.

(iii) The SEP begins and ends concurrently with the additional Part D Initial Election Period.

(23) Individuals affected by a significant change in plan provider network are eligible for a SEP that permits disenrollment from the MA plan that has changed its network to another MA plan or to original Medicare. This SEP can be used only once per significant change in the provider network.

(i) The SEP begins the month the individual is notified of eligibility for the SEP and extends an additional 2 calendar months thereafter.

(ii) An enrollee is affected by a significant network change when the enrollee is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated from the provider network.

(iii) When instructed by CMS, the MA plan that has significantly changed its network must issue a notice, in the form and manner directed by CMS, that notifies enrollees who are eligible for this SEP of their eligibility for the SEP and how to use the SEP.

(24) The individual is enrolled in a plan offered by an MA organization that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(25) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 422.166(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing MA plan.

(26) The individual enrolls in Medicare premium-Part A or Part B using an exceptional condition SEP, as described in 42 CFR 406.27 and 407.23. The SEP begins when the individual submits their application for premium-Part A and Part B, or Part B only, if the individual is already entitled to Part A (or is enrolling in premium-free Part A within the timeframe for use of this SEP), and continues for the first 2 months beyond the premium-Part A and/or Part B entitlement date. The MA plan enrollment is effective the first of the month following the month the MA plan receives the enrollment request.

(27) 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; 76 FR 21561, Apr. 15, 2011; 83 FR 16722, Apr. 16, 2018; 85 FR 33901, June 2, 2020; 88 FR 22328, Apr. 12, 2023; 88 FR 50044, Aug. 1, 2023]

§ 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*—(1) *Basic rule.* Subject to paragraph (c)(2) of this section, an individual who fails to make an election during the initial coverage election period is deemed to have elected original Medicare.

(2) *Default enrollment into MA dual eligible special needs plan*—(i) *Conditions for default enrollment.* During an individual's initial coverage election period, an individual may be deemed to have elected a MA special needs plan for individuals entitled to medical assistance under a State plan under Title XIX (including a fully integrated dual eligible special needs plan as defined in § 422.2) offered by the organization provided all the following conditions are met:

(A) At the time of the deemed election, the individual remains enrolled in an affiliated Medicaid managed care plan. For purposes of this section, an affiliated Medicaid managed care plan is one that is offered by the MA organization that offers the dual eligible MA special needs plan or is offered by an entity that shares a parent organization with such MA organization;

(B) The state has approved the use of the default enrollment process in the contract described in § 422.107 and provides the information that is necessary for the MA organization to identify individuals who are in their initial coverage election period;

(C) The MA organization offering the MA special needs plan has issued the notice described in paragraph (c)(2)(iv) of this section to the individual;

(D) Prior to the effective date described in paragraph (c)(2)(iii) of this section, the individual does not decline the default enrollment and does not elect to receive coverage other than through the MA organization;

(E) CMS has approved the MA organization to use default enrollment under paragraph (c)(2)(ii) of this section;

(F) The MA organization has a minimum overall quality rating from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252; and

(G) The MA organization does not have any prohibition on new enrollment imposed by CMS.

(ii) *CMS approval of default enrollment.* An MA organization must obtain approval from CMS before implementing any default enrollment as described in this section. CMS approval will be for a period not to exceed five years, although CMS may suspend or rescind approval prior to the expiration of this period if CMS determines the MA organization is not in compliance with the requirements of this section.

(iii) *Effective date of default enrollment.* Default enrollment in the dual eligible MA special needs plan is effective the month in which the individual is first entitled to both Part A and Part B.

(iv) *Notice requirement for default enrollments.* In addition to the information described in § 422.111 and no fewer than 60 calendar days prior to the enrollment effective date described in paragraph (c)(2)(iii) of this section, the MA organization must provide to each individual who qualifies for deemed enrollment under paragraph (c)(2) of this section a notice that includes the following:

(A) Information on the differences in premium, benefits and cost sharing between the individual's current Medicaid managed care plan and the dual eligible MA special needs plan and the process for accessing care under the MA plan;

(B) The individual's ability to decline the enrollment, up to and including the day prior to the enrollment effective date, and either enroll in Original Medicare or choose another MA plan; and

(C) A general description of alternative Medicare health and drug coverage options available to an individual in his or her Initial Coverage Election Period.

(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 requests enrollment during his or her Initial Coverage Election Period while enrolled in a health plan offered by the MA organization during the month immediately preceding the MA plan enrollment effective date, 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.* An individual who requests seamless continuation of coverage as described in paragraph (d)(1) of this section may complete a simplified election, in a form and manner approved by CMS that meets the requirements in § 422.60(c)(1).

(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; 83 FR 16722, Apr. 16, 2018]

§ 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 follows:

(1) If made prior to the month of entitlement to both Part A and Part B, it is effective as of the first day of the month of entitlement to both Part A and Part B.

(2) If made during or after the month of entitlement to both Part A and Part B, it is effective the first day of the calendar month following the month in which the election is made.

(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 (5), 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 coverage or

change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

(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.

(f) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Through 2018, an election made from January 1 through February 14 to disenroll from an MA plan to Original Medicare, as described in § 422.62(a)(5), is effective the first day of the first 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; 76 FR 21562, Apr. 15, 2011; 83 FR 16724, Apr. 16, 2018; 85 FR 33903, June 2, 2020]

§ 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).

(v) The individual is not lawfully present in the United States.

(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) Except as specified in paragraph (d)(1)(iv) of this section, 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 must—

(*1*) Be at least 2 months; and

(*2*) Begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later.

(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.

(iv) An MA organization may not disenroll an individual who had monthly premiums withheld per § 422.262(f)(1) and (g) of this part, or who is in premium withhold status, as defined by CMS.

(v) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as an MA organization) may reinstate enrollment in the MA plan, without interruption of coverage, if the individual—

(A) Shows good cause for failure to pay within the initial grace period; and

(B) Pays all overdue premiums within 3 calendar months after the disenrollment date; and

(C) Establishes by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(vi) *No extension of grace period.* A beneficiary's enrollment in the MA plan may not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

(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 is incarcerated as specified in paragraph (d)(4)(v) of this section.

(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 offers a visitor/traveler benefit when the individual is out of the service area but within the United States (as defined in § 400.200 of this chapter) for a period of consecutive days longer than 6 months but less than 12 months, 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, consistent with paragraph (d)(4)(i)(C) of the section;

(C) The MA organization makes this visitor/traveler option available to all Medicare enrollees who are absent for an extended period from the MA plan's service area. MA organizations may limit this visitor/traveler 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; and

(D) The MA organization furnishes all Medicare Parts A and B services and all mandatory and optional supplemental benefits at the same cost sharing levels as apply within the plan's service area; and

(E) The MA organization furnishes the services in paragraph (d)(4)(iii)(D) of this section consistent with Medicare access and availability requirements at § 422.112 of this part.

(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.

(v) *Incarceration.* (A) The MA organization must disenroll an individual if the MA organization establishes, on the basis of evidence acceptable to CMS, that the individual is incarcerated and does not reside in the service area of the MA plan as specified at § 422.2 or when notified of the incarceration by CMS as specified in paragraph (d)(4)(v)(B) of this section.

(B) *Notification by CMS of incarceration.* When CMS notifies the MA organization of the disenrollment due to the individual being incarcerated and not residing in the service area of the MA plan as per § 422.2, disenrollment is effective the first of the month following the start of incarceration, unless otherwise specified by CMS.

(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).

(8) *Enrollee is not lawfully present in the United States.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with § 417.422(h) of this chapter.

(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; 74 FR 1541, Jan. 12, 2009; 75 FR 19804, Apr. 15, 2010; 76 FR 21562, Apr. 15, 2011; 79 FR 29955, May 23, 2014; 80 FR 7959, Feb. 12, 2015]

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)(1) of this section (except that additional telehealth benefits may be, but are not required to be, offered by the MA plan) and, to the extent applicable, supplemental benefits as described in paragraph (c)(2) of this section, by furnishing the benefits directly or through arrangements, or by paying for the benefits. CMS reviews these benefits subject to the requirements of this section 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 items and services (other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135.

(2) Supplemental benefits are benefits offered under § 422.102.

(i) Supplemental benefits consist of—

(A) 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.

(B) 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.

(ii) Supplemental benefits must meet the following requirements:

(A) Except in the case of special supplemental benefit for the chronically ill (SSBCI) offered in accordance with § 422.102(f) that are not primarily health related, the benefits diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health conditions; or reduce avoidable emergency and health care utilization;

(B) The MA organization incurs a non-zero direct medical cost, except that in the case of a SSBCI that is not primarily health related that is offered in accordance with § 422.102, the MA organization may instead incur a non-zero direct non-administrative cost; and

(C) The benefits are not covered by Medicare (This specifically includes Medicare Parts A, B, and D).

(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)(i) 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).

(ii) MA plans may provide supplemental benefits (such as specific reductions in cost sharing or additional services or items) that are tied to disease state or health status in a manner that ensures that similarly situated individuals are treated uniformly; there must be some nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state.

(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 and associated cost sharing.* CMS reviews and approves MA benefits and associated cost sharing using written policy guidelines and requirements in this part and other CMS instructions to ensure all of the following:

(1) *Guidelines.* Medicare-covered services meet CMS fee-for-service guidelines.

(2) *Discrimination.* 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.

(3) *Other requirements.* Benefit design meets other MA program requirements.

(4) *In-network MOOP limit.* Except as provided in paragraph (f)(5) of this section, MA local plans (as defined in § 422.2) must have an enrollee in-network maximum out-of-pocket (MOOP) amount for basic benefits that is no greater than the annual limit calculated by CMS using Medicare Fee-for-Service (FFS) data projections. With respect to a private fee-for-service (PFFS) plan, the in-network MOOP limits specified in this paragraph (f)(4) apply. MA organizations are responsible for tracking out-of-pocket spending accrued by the enrollee, and must alert enrollees and contracted providers when the plan's in-network MOOP amount is reached.

(i) *Medicare FFS data projections in CMS MOOP limit calculations.* For each year beginning on or after January 1, 2023, CMS calculates three MOOP limits using Medicare FFS data projections. For purposes of this paragraph (f)(4) and calculating actuarially equivalent copayments as described in paragraph (f)(7) of this section, the term *Medicare FFS data projections* means the projections of beneficiary out-of-pocket costs for the applicable contract year, based on recent Medicare FFS data, including data for beneficiaries with and without diagnoses of ESRD, that are consistent with generally accepted actuarial principles and practices as outlined in paragraph (f)(7)(i) of this section. The dollar ranges for the three MOOP limits are as follows:

(A) *Mandatory MOOP limit.* One dollar above the intermediate MOOP limit and up to and including the mandatory MOOP limit.

(B) *Intermediate MOOP limit.* One dollar above the lower MOOP limit and up to and including the intermediate MOOP limit.

(C) *Lower MOOP limit.* Between $0.00 and up to and including the lower MOOP limit.

(ii) *MOOP type.* An MA organization that establishes a plan's MOOP amount within the dollar range specified in paragraphs (f)(4)(i)(A) through (C) of this section has the corresponding mandatory, intermediate, or lower MOOP type for purposes of paragraphs (f) and (j) of this section and §§ 422.101(d) and 422.113(b)(2)(v).

(iii) *CMS rounding of MOOP limits.* Each MOOP limit CMS calculates is rounded to the nearest $50 increment and in cases where the MOOP limit is projected to be exactly in between two $50 increments, CMS rounds to the lower $50 increment.

(iv) *MOOP limits for 2023.* For 2023, CMS calculates the MOOP limits as follows, applying paragraph (f)(4)(vi)(A) of this section:

(A) *Mandatory MOOP limit.* $7,175 (the 95th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: The resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the mandatory MOOP limit from the prior year, in which case CMS caps the increase to the mandatory MOOP limit by 10 percent of the prior year's MOOP limit.

(B) *Intermediate MOOP limit.* The numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) of this section and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraphs (f)(4)(iv)(A) and (C) of this section).

(C) *Lower MOOP limit.* $3,360 (the 85th percentile of projected contract year 2021 Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD) plus 70 percent of the ESRD cost differential unless: The resulting MOOP limit (after application of the rounding rules in paragraph (f)(4)(iii) of this section) reflects an increase greater than 10 percent compared to the voluntary MOOP limit from the prior year, in which case CMS caps the increase to the lower MOOP limit by 10 percent of the prior year's MOOP limit.

(v) *MOOP limits for 2024 and subsequent years.* For 2024 and subsequent years, CMS annually calculates the MOOP limits as follows, applying paragraph (f)(4)(vi)(B) of this section:

(A) *Mandatory and lower MOOP limits.* The prior year's MOOP limits are increased or decreased for the upcoming contract year to reflect the applicable percentiles (95th for the mandatory MOOP and 85th for the lower MOOP) of the Medicare FFS data projections unless: Either of the resulting MOOP limits reflect an increase greater than 10 percent compared to the same type of MOOP limit from the prior year, in which case CMS caps the increase to the applicable MOOP limit(s) by 10 percent of the prior year's MOOP limit annually until the MOOP limit(s) reflects the applicable percentile(s).

(B) *Intermediate MOOP limit.* Is either maintained at the prior year's limit or if either the mandatory or lower MOOP limit changes from the prior year, updated to the new numeric midpoint between the mandatory and lower MOOP limits (calculated before application of the rounding rules in paragraph (f)(4)(iii) of this section and after application of the 10-percent cap on increases to the mandatory and lower MOOP limits from the prior year in paragraph (f)(4)(v)(A) of this section).

(vi) *CMS calculation of the ESRD cost differential.* For purposes of the ESRD cost transition methodology to calculate annual MOOP limits contained in this section, the *ESRD cost differential* is the difference between, first, for the mandatory MOOP limit, $7,175 and for the lower MOOP limit, $3,360 and second, for the mandatory MOOP limit, the 95th percentile and, for the lower MOOP limit, the 85th percentile of the Medicare FFS data projections for each year between 2023 and 2024. CMS transitions to using the Medicare FFS data projections by factoring in a percentage of the ESRD cost differential on the following schedule:

(A) For 2023, CMS uses projected Medicare FFS beneficiary out-of-pocket spending for beneficiaries without diagnoses of ESRD plus 70 percent of the ESRD cost differential.

(B) For 2024 and subsequent years, CMS uses the Medicare FFS data projections.

(5) *Combined MOOP limit.* With respect to a local PPO plan, the MOOP limits specified under paragraph (f)(4) of this section apply only to use of in-network providers.

(i) *Combined and total catastrophic MOOP limits.* MA local PPO plans must establish a combined enrollee MOOP

amount for basic benefits that are provided in-network and out-of-network that is no greater than the total catastrophic limit applicable to regional plans in § 422.101(d)(3).

(ii) *In-network and combined MOOP type.* The type of in-network MOOP limit dictates the type of combined MOOP limit the MA plan may use. MA PPO plans must have the same MOOP type (lower, intermediate, or mandatory) for the in-network MOOP limit and combined limit on in-network and out-of-network out-of-pocket expenditures.

(iii) *MOOP limit attainment.* MA organizations are responsible for tracking out-of-pocket spending accrued by the enrollee and must alert enrollees and contracted providers when the combined MOOP amount is reached.

(6) *General cost sharing limits.* Cost sharing for basic benefits specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services. For each year beginning on or after January 1, 2023, a MA organization must establish cost sharing for basic benefits that complies with the cost sharing limits in this paragraph (f)(6), paragraph (j) of this section, and § 422.113(b)(2), which are in addition to any other limits and rules applicable to MA cost sharing, including the requirement in § 422.254(b)(4) that overall MA cost sharing for basic benefits be actuarially equivalent to Medicare FFS cost sharing. Cost sharing may be a coinsurance or copayment; a cost sharing limit is calculated for a plan benefit package service category or for a reasonable group of benefits covered under the plan. For purposes of cost sharing evaluation, the analysis is completed at the plan (or segment) level. An MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s).

(i) *The 50 percent cap on original Medicare benefits.* For in-network basic benefits that are not specifically addressed in this paragraph (f)(6), paragraph (j)(1) of this section, or § 422.113(b)(2), and for out-of-network basic benefits, MA plans must not establish a cost sharing amount that exceeds 50 percent coinsurance or an actuarially equivalent copayment value (calculated by CMS following the requirements in paragraph (f)(7) of this section or, if CMS does not calculate a copayment limit, based on the average Medicare FFS allowable amount for the plan service area or the estimated total MA plan financial liability for the service category or for a reasonable group of benefits in the PBP for that contract year). The rules in this paragraph (f)(6)(i) apply regardless of the type of MOOP limit established by the plan.

(ii) *Copayment rounding rules.* The following rounding rules apply in calculating copayment limits and in evaluating compliance with this paragraph (f)(6) and paragraphs (f)(7), (f)(8), and (j)(1) of this section:

(A) For service categories subject to paragraph (f)(6)(i) of this section, professional services subject to paragraph (f)(6)(iii) of this section, and benefits listed in paragraph (j)(1)(i) of this section, the final actuarially equivalent copayment value is rounded to the nearest whole $5.

(B) For inpatient hospital acute and psychiatric and skilled nursing facility cost sharing limits subject to paragraphs (f)(6)(iv) and (j)(1)(i)(C) of this section, the final actuarially equivalent copayment value is rounded to the nearest whole $1.

(C) When the actuarially equivalent copayment value is projected to be exactly between two increments, the final figure is rounded to the lower dollar amount.

(iii) *Cost sharing limits for professional services.* (A) For in-network basic benefits that are professional services, including primary care services, physician specialist services, partial hospitalization, and rehabilitation services, an MA plan must not establish cost sharing that exceeds the limits in this paragraph (f)(6)(iii) for the MOOP limit established by the MA plan.

(B) When calculating copayment limits for purposes of this paragraph, CMS calculates an actuarially equivalent value to the coinsurance limits in this paragraph (f)(6)(iii), subject to the requirements in paragraph (f)(7) of this section and the restrictions on increases to copayment limits in paragraph (f)(8) of this section. If CMS does not calculate a copayment limit for a professional service category, the MA

plan must not establish a copayment that exceeds the actuarially equivalent value to the coinsurance limits in this paragraph (f)(6)(iii) based on the estimated total MA plan financial liability for that benefit for that contract year.

(C) For 2023, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 45 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 55 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 47 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 53 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(D) For 2024, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 40 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 60 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 45 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 55 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(E) For 2025, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 35 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 65 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 42 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 58 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(F) For 2026 and subsequent years, MA plans must not exceed the cost sharing limits for professional service categories, as follows:

(*1*) *Mandatory MOOP limit.* 30 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 70 percent of the estimated total MA plan financial liability for the benefit.

(*2*) *Intermediate MOOP limit.* 40 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 60 percent of the estimated total MA plan financial liability for the benefit.

(*3*) *Lower MOOP limit.* 50 percent coinsurance or an actuarially equivalent copayment value and the MA plan must not pay less than 50 percent of the estimated total MA plan financial liability.

(iv) *Inpatient hospital acute and psychiatric service category cost sharing limits.* (A) For in-network basic benefits that are inpatient hospital acute and psychiatric service categories, an MA plan must not establish cost sharing that exceeds the limits calculated by CMS under paragraph (f)(6)(iv) of this section and subject to paragraph (f)(7) of this section for the MOOP limit established by the MA plan.

(B) Cost sharing limits for inpatient hospital acute and psychiatric service categories are calculated for the following seven length-of-stay scenarios for a period for which cost sharing would apply under original Medicare: Inpatient hospital acute stay scenarios of 3 days, 6 days, 10 days, and 60 days and inpatient hospital psychiatric stay scenarios of 8 days, 15 days, and 60 days.

(C) CMS calculates the inpatient hospital acute and psychiatric service category cost sharing limits annually using projections of Medicare FFS out-of-pocket costs and utilization for the

applicable year and length of stay scenario and factors in out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD on the transition schedule described in paragraphs (f)(4)(vi)(A) through (B) of this section and may also use patient utilization information from MA encounter data.

(D) Provided that the total cost sharing for the inpatient benefit does not exceed the MA plan's MOOP limit or overall cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis, cost sharing applicable to inpatient hospital acute and psychiatric service categories is permitted up to the following limits (based on original Medicare cost sharing for a new benefit period):

(*1*) *Mandatory MOOP limit.* Cost sharing must not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay scenario.

(*2*) *Intermediate MOOP limit.* Cost sharing must not exceed the numeric midpoint between the cost sharing limits established in paragraphs (f)(6)(iv)(D)(*1*) and (*3*) of this section for the same inpatient hospital length of stay scenario, before application of the rounding rules in paragraph (f)(6)(ii) of this section.

(*3*) *Lower MOOP limit.* Cost sharing must not exceed 125 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length of stay scenario other than the inpatient hospital acute 60-day length-of-stay for MA plans that establish a lower MOOP limit. For inpatient hospital acute 60-day length of stays, MA plans that establish a lower MOOP limit have the flexibility to establish cost sharing above 125 percent of estimated Medicare FFS cost sharing.

(7) *Using generally accepted actuarial principles and practices.* (i) *Application of generally accepted actuarial principles and practices.* The projections and calculations used in the methodologies described in paragraphs (f)(4), (f)(5), (f)(6), (f)(7)(ii), (f)(8), and (j) of this section and in § 422.101(d)(2) and (3) must be made using generally accepted actuarial principles and practices.

(A) In applying generally accepted actuarial principles and practices, actuarial judgment and discretion may be used, including taking into account information such as changes in legislation (such as changes in Medicare benefits), Medicare payment policy, trends over several years of data, and external variables (such as public health emergencies); selecting among different approaches (such as weighting for utilization and using average or median values); and in selecting data or data samples.

(B) MA organizations must use generally accepted actuarial principles and practices in complying with the regulations in paragraphs (f)(6) and (j) of this section.

(C) CMS applies generally accepted actuarial principles and practices in evaluating MA plan compliance with paragraphs (f)(6) and (j) of this section.

(ii) *CMS calculation of actuarially equivalent copayment limits.* As feasible and appropriate to carry out program purposes, CMS calculates copayment limits for basic benefits in accordance with paragraphs (f)(6)(i) and (iii) and (j)(1) of this section. Beginning January 1, 2023, unless specified otherwise in paragraphs (f)(6) and (j)(1) of this section, CMS calculates these copayment limits at an actuarially equivalent value to the cost sharing standard as follows:

(A) Using Medicare FFS data projections, as defined in paragraph (f)(4)(i) of this section, for the applicable year and service category.

(B) Using patient utilization information from MA encounter data, in addition to the Medicare FFS data projections (including cost and utilization data), if available and where appropriate to consider utilization differences between Medicare FFS beneficiaries and MA enrollees to reach a value that most closely reflects an actuarially equivalent copayment for the benefit and beneficiary population.

(C) Selecting a particular approach to calculate an actuarially equivalent copayment value in situations where there may be multiple or a range of actuarially equivalent copayment values for a service category in order to carry

out program purposes, including: Setting copayment limits that most closely reflect an actuarially equivalent copayment for the benefit and beneficiary population, protecting against discriminatory cost sharing, and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries.

(D) Applying the actuarially equivalent copayment transition in paragraph (f)(8) of this section.

(E) Applying rounding rules in paragraph (f)(6)(ii) of this section.

(iii) *CMS issuance of annual guidance.* CMS issues guidance that specifies the MOOP limits and cost sharing standards for the upcoming contract year (beginning with contract year 2024) that are set and calculated using the methodology and standards in paragraphs (f) and (j) of this section and §§ 422.101(d) and 422.113. This guidance is released prior to bid submission to allow sufficient time for MA organizations to prepare and submit plan bids. Unless a public comment period is impracticable, unnecessary, or contrary to the public interest, CMS provides a public notice and comment period on the projected MOOP limits and cost sharing standards for the upcoming contract year.

(8) *Annual cap on CMS increasing copayment limits during the actuarially equivalent copayment transition.* For 2023 through 2025, CMS sets a copayment limit for a service category subject to paragraph (f)(6)(iii) or (j)(1) of this section at an amount that is the lesser of an actuarially equivalent value to the applicable cost sharing standard (from paragraph (f)(6)(iii) or (j)(1) of this section) or the value resulting from the actuarially equivalent copayment transition in paragraph (f)(8)(ii) of this section for that service category.

(i) CMS *calculation of the actuarially equivalent copayment differential.* For purposes of this section, the actuarially equivalent copayment differential is as follows:

(A) For cost sharing at the mandatory and lower MOOP limits, the difference between, first, the copayment limit set for a plan benefit package service category based on the MOOP type for 2022 and second, the copayment value for the same service category that is actuarially equivalent to the coinsurance limits in paragraphs (f)(6)(iii) and (j)(1) of this section that apply in 2026 based on the MOOP type, using the Medicare FFS data projections that are updated each year to reflect the costs of the contract year for which the copayment limit will apply.

(B) For cost sharing at the intermediate MOOP limit, the difference between, first, the copayment limit set for a plan benefit package service category based on the mandatory MOOP type for 2022 and second, the copayment value for the same service category that is actuarially equivalent to the coinsurance limits in paragraphs (f)(6)(iii) and (j)(1) of this section that apply in 2026 for the intermediate MOOP type, using the Medicare FFS data projections that are updated each year to reflect the costs of the contract year for which the copayment limit will apply.

(ii) *CMS's actuarially equivalent copayment transition.* For service categories subject to the cost sharing standards in paragraphs (f)(6)(iii) and (j)(1) of this section, copayment limits calculated by CMS for 2023 through 2025 are capped at the amounts calculated under this paragraph, unless specified otherwise in paragraph (f)(8) of this section, rounded as provided in paragraph (f)(6)(ii) of this section:

(A) For 2023, CMS uses the copayment limits set for 2022 plus 25 percent of the actuarially equivalent copayment differential.

(B) For 2024, CMS uses the copayment limits set for 2022 plus 50 percent of the actuarially equivalent copayment differential.

(C) For 2025, CMS uses the copayment limits set for 2022 plus 75 percent of the actuarially equivalent copayment differential.

(D) For 2026 and subsequent years, CMS calculates service category copayment limits at the projected actuarially equivalent value to the cost sharing standards in paragraphs (f)(6)(iii)(F) and (j)(1) of this section and subject to paragraph (f)(7) of this section.

(9) *Bundled cost sharing.* Cost sharing (copayments and coinsurance) for basic

benefits must reflect the enrollee's entire cost sharing responsibility, inclusive of professional, facility, or provider setting charges, by combining (or bundling) all applicable fees into the cost sharing amount for that particular service(s) and setting(s) and be clearly reflected as a single, total cost sharing in appropriate materials distributed to beneficiaries for basic benefits.

(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.

(j) *Cost sharing and actuarial equivalence standards for basic benefits*—(1) *Specific benefits for which cost sharing may not exceed cost sharing under original Medicare.* (i) *General rule.* For each year beginning on or after January 1, 2023, in-network cost sharing established by an MA plan for the basic benefits listed in this paragraph may not exceed the cost sharing required under original Medicare. When an MA plan uses coinsurance, the coinsurance must not exceed the coinsurance charged in original Medicare. When an MA plan uses copayments, the copayment must not exceed the actuarially equivalent value calculated using the rules in paragraph (j)(1)(ii) of this section. The benefits listed in this paragraph are as follows:

(A) Chemotherapy administration services to include chemotherapy/radiation drugs and radiation therapy integral to the treatment regimen.

(B) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(C) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare, when the MA plan establishes the mandatory MOOP type; when the MA plan establishes the lower MOOP type, the cost sharing must not be greater than $20 per day for the first 20 days of a SNF stay; when the MA plan establishes the intermediate MOOP type, the cost sharing must not be greater than $10 per day for the first 20 days of a SNF stay.

(1) Regardless of the MOOP amount established by the MA plan, the per-day cost sharing for days 21 through 100 must not be greater than one eighth of the projected (or actual) Part A deductible amount.

(2) Total cost sharing for the overall SNF benefit must not be greater than the per member per month actuarially equivalent cost sharing for the SNF benefit in original Medicare.

(D) Home health services (as defined in section 1861(m) of the Act), when the MA plan establishes a mandatory or intermediate MOOP type; when the MA plan establishes the lower MOOP type, the cost sharing must not be greater than 20 percent coinsurance or an actuarially equivalent copayment.

(E) The following specific service categories of durable medical equipment (DME): Equipment, prosthetics, medical supplies, diabetes monitoring supplies, diabetic shoes or inserts when the MA plan establishes the mandatory MOOP limit. For all MOOP limits, total cost sharing for the overall DME benefit must not be greater than the per member per month actuarially equivalent cost sharing for the DME benefit in original Medicare.

(F) Other drugs covered under Part B of original Medicare (that is, Part B drugs not included in paragraph (j)(1)(i)(A) of this section).

(ii) *Rules for calculating copayment limits.* For 2023 and subsequent years, CMS calculates copayment limits for the basic benefits listed in paragraph (j)(1)(i) of this section subject to the requirements in paragraph (f)(7) of this section and the restrictions on increases to copayment limits in paragraph (f)(8) of this section. If CMS does

not calculate a copayment limit for a benefit listed in paragraph (j)(1)(i) of this section, an MA plan must establish a copayment that does not exceed an actuarially equivalent value to the coinsurance required under original Medicare; such actuarially equivalent value must be established in accordance with paragraph (f)(7)(i) of this section and based on the average Medicare FFS allowed amount in the plan's service area or the estimated total MA plan financial liability for that benefit for that contract year.

(2) *Actuarially equivalent cost sharing evaluation for all basic benefits and specific categories of basic benefits in the aggregate.* For each year beginning on or after January 1, 2023, an MA plan's total cost sharing for all basic benefits, excluding out of network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.

(i) MA plans must have cost sharing for the following specific benefit categories that does not exceed the cost sharing for those benefit categories in original Medicare on a per member per month actuarially equivalent basis:

(A) Inpatient hospital acute and psychiatric services, defined as services provided during a covered inpatient stay during the period for which cost sharing would apply under original Medicare.

(B) Durable medical equipment (DME).

(C) Drugs and biologics covered under Part B of original Medicare.

(D) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare.

(ii) CMS may extend flexibility for MA plans when evaluating compliance with the requirements in paragraph (j)(2)(i) of this section regarding actuarial equivalent cost sharing for all basic benefits and specific categories of basic benefits to the extent that it is actuarially justifiable provided that the MA plan's cost sharing is based on generally accepted actuarial principles and practices (consistent with paragraph (f)(7) of this section), supporting documentation included in the bid, and the MA plan's cost sharing for specific service categories otherwise satisfies applicable cost sharing standards.

(k) *Cost sharing for in-network preventive services.* MA organizations may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in § 410.152(l)).

(l) Coverage of DME. MA organizations—

(1) Must cover and ensure enrollees have access to all categories of DME covered under Part B; and

(2) May, within specific categories of DME, limit coverage to certain DME brands, items, and supplies of preferred manufacturers provided the MA organization ensures all of the following:

(i) Its contracts with DME suppliers ensure that enrollees have access to all DME brands, items, and supplies of preferred manufacturers.

(ii) Its enrollees have access to all medically-necessary DME brands, items, and supplies of non-preferred manufacturers.

(iii) At the enrollees' request, it provides for an appropriate transition process for new enrollees during the first 90 days of their coverage under its MA plan, during which time the MA organization will do the following:

(A) Ensure the provision of a transition supply of DME brands, items, and supplies of non-preferred manufacturers.

(B) Provide for the repair of DME brands, items, and supplies of non-preferred manufacturers.

(iv) It makes no negative changes to its DME brands, items, and supplies of preferred manufacturers during the plan year.

(v) It treats denials of DME brands, items, and supplies of non-preferred manufacturers as organization determinations subject to § 422.566.

(vi) It discloses DME coverage limitations and beneficiary appeal rights in the case of a denial of a DME brand, item, or supply of a non-preferred manufacturer as part of the description of benefits required under § 422.111(b)(2) and § 422.111(h).

(vii) It provides full coverage, without limitation on brand and manufacturer, to all DME categories or subcategories annually determined by CMS to require full coverage.

(m) *Special requirements during a disaster or emergency.* (1) When a disaster or emergency is declared as described in paragraph (m)(2) of this section and there is disruption of access to health care as described in paragraph (m)(6) of this section, an MA organization offering an MA plan must, until the end date specified in paragraph (m)(3) of this section occurs, ensure access to covered benefits in the following manner:

(i) Cover Medicare Parts A and B services and supplemental Part C plan benefits furnished at non-contracted facilities subject to § 422.204(b)(3).

(ii) Waive, in full, requirements for gatekeeper referrals where applicable.

(iii) Provide the same cost-sharing for the enrollee as if the service or benefit had been furnished at a plan-contracted facility.

(iv) Make changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3).

(2) *Declarations of disasters.* A declaration of a disaster or emergency will identify the geographic area affected by the event and may be made as one of the following:

(i) Presidential declaration of a disaster or emergency under the either of the following:

(A) Stafford Act.

(B) National Emergencies Act.

(ii) Secretarial declaration of a public health emergency under section 319 of the Public Health Service Act.

(iii) Declaration by the Governor of a State or Protectorate.

(3) *End of the special requirements for the disaster or emergency.* An MA organization must continue furnishing access to benefits as specified in paragraphs (m)(1)(i) through (iv) of this section for 30 days after the conditions described in paragraph (m)(3)(i) or (ii) of this section occur with respect to all applicable emergencies or after the condition described in paragraph (m)(3)(iii) of this section occurs, whichever is earlier:

(i) All sources that declared a disaster or emergency that include the service area declare an end.

(ii) No end date was identified as described in paragraph (m)(3)(i) of this section, and all applicable emergencies or disasters declared for the area have ended, including through expiration of the declaration or any renewal of such declaration.

(iii) There is no longer a disruption of access to health care as defined in paragraph (m)(6) of this section.

(4) *MA plans unable to operate.* An MA plan that cannot resume normal operations by the end of the disaster or emergency as described in paragraph (m)(3)(i) or (ii) of this section must notify CMS.

(5) *Disclosure.* In addition to other requirements of annual disclosure under § 422.111, an organization must do all of the following:

(i) Indicate the terms and conditions of payment during the disaster or emergency for non-contracted providers furnishing benefits to plan enrollees residing in the affected service area(s).

(ii) Annually notify enrollees of the information listed in paragraphs (m)(1) through (3) and (m)(5) of this section.

(iii) Provide the information described in paragraphs (m)(1), (2), and (3) and (m)(5)(i) of this section on its website.

(6) *Disruption of access to health care.* A disruption of access to health care for the purpose of paragraph (m) of this section is an interruption or interference in the service area (as defined at § 422.2) such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services to enrollees, resulting in MA plans failing to meet the normal prevailing patterns of community health care delivery in the service area under § 422.112(a).

(n) *Digital health education program.* MA organizations must establish procedures to identify and offer digital health education to enrollees with low digital health literacy to assist with accessing any medically necessary covered benefits that are furnished when the enrollee and the provider are not in

the same location using electronic exchange, as defined in § 422.135.

(1) The MA organization must make information about its digital health literacy screening and digital health education programs available to CMS upon request. Requested information may include, but is not limited to, statistics on the number of enrollees identified with low digital health literacy and receiving digital health education, manner(s) or method of digital health literacy screening and digital health education, financial impact of the programs on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of this section.

(2) [Reserved]

[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; 75 FR 19804, Apr. 15, 2010; 76 FR 21562, Apr. 15, 2011; 77 FR 22166, Apr. 12, 2012; 80 FR 7959, Feb. 12, 2015; 83 FR 16724, Apr. 16, 2018; 84 FR 15828, Apr. 16, 2019; 86 FR 6094, Jan. 19, 2021; 87 FR 22423, Apr. 14, 2022; 87 FR 27893, May 9, 2022; 88 FR 22328, Apr. 12, 2023]

§ 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 and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. For example, this includes payment criteria for inpatient admissions at 42 CFR 412.3, services and procedures that the Secretary designates as requiring inpatient care under 42 CFR 419.22(n), and requirements for payment of Skilled Nursing Facility (SNF) Care, Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities (IRF) at 42 CFR 412.622(a)(3).

(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.

(6) MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.

(i) *Coverage criteria not fully established.* Coverage criteria are not fully established when:

(A) additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. The MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services;

(B) NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or

(C) There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria.

(ii) *Publicly accessible.* For internal coverage policies, the MA organization must provide in a publicly accessible way the following:

(A) The internal coverage criteria in use and a summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations;

(B) A list of the sources of such evidence; and

(C) An explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. When coverage criteria are not fully established as described in paragraph (6)(i)(A), the MA organization must identify the general provisions that are being supplemented or interpreted and explain how the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

(c) Medical necessity determinations and special coverage provisions—(1) *Medical necessity determinations.* (i) MA organizations must make medical necessity determinations based on all of the following:

(A) Coverage and benefit criteria as specified at paragraphs (b) and (c) of this section and may not deny coverage for basic benefits based on coverage criteria not specified in paragraph (b) or (c) of this section.

(B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act.

(C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.

(D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

(ii) [Reserved]

(2) *Exception for qualifying hospital stay.* 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 and local PPO plans, to the extent they apply a deductible as follows:

(i) Must have a single deductible related to all in-network and out-of-network Medicare Part A and Part B services.

(ii) May specify separate deductible amounts for specific in-network Medicare Part A and Part B services, to the extent these deductible amounts apply to the single deductible amount specified in paragraph (d)(1)(i) of this section.

(iii) May waive other plan-covered items and services from the single deductible described in paragraph (d)(1)(i) of this section.

(iv) Must waive all Medicare-covered preventive services (as defined in § 410.152(l)) from the single deductible described paragraph (d)(1)(i) of this section.

(2) *Catastrophic limit.* For each year beginning on or after January 1, 2023, MA regional plans must do the following:

(i) Establish a catastrophic enrollee MOOP amount for basic benefits that are furnished by in-network providers that is consistent with § 422.100(f)(4).

(ii) Have the same MOOP type (lower, intermediate, or mandatory) for the catastrophic (in-network MOOP) limit and total catastrophic (combined in-network and out-of-network expenditures) limit under paragraph (d)(3) of this section.

(3) *Total catastrophic limit.* For each year beginning on or after January 1, 2023, MA regional plans must establish a total catastrophic (combined in-network and out-of-network expenditures) enrollee MOOP amount for basic benefits that is consistent with this paragraph (d)(3).

(i) The total catastrophic limit may not be used to increase the catastrophic limit described in paragraph (d)(2) of this section.

(ii) CMS calculates the total catastrophic limits by multiplying the respective in-network MOOP limits (before the rounding rules in § 422.100(f)(4)(iii) are applied and after application of the 10 percent cap on increases to the mandatory and lower MOOP limits from the prior year in § 422.100(f)(4)(iv) and (v)) by 1.5 for the relevant year, then applying the rounding rules in § 422.100(f)(4)(iii). The dollar ranges for the three total catastrophic MOOP limits are as follows:

(A) *Mandatory MOOP limit.* One dollar above the in-network intermediate MOOP limit and up to and including the total catastrophic mandatory MOOP limit.

(B) *Intermediate MOOP limit.* One dollar above the in-network lower MOOP limit and up to and including the total catastrophic intermediate MOOP limit.

(C) *Lower MOOP limit.* Between $0.00 and up to and including the total catastrophic lower MOOP limit.

(iii) An MA organization must establish the total catastrophic MOOP amount (mandatory, intermediate, or lower) within the dollar range specified in paragraphs (d)(3)(ii)(A) through (C) of this section for purposes of paragraph (d) of this section and §§ 422.100(f)(6), (j)(1), and 422.113(b)(2)(v).

(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 (3) of this section based on accrued 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.

(f) *Special needs plan model of care.* (1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled, do all of the following:

(i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that the results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individuals' individualized care plan as required under paragraph (f)(1)(ii) of this section. Beginning in 2024, the comprehensive risk assessment tool must include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on each of the following domains:

(A) Housing stability;

(B) Food security; and

(C) Access to transportation.

(ii) Develop and implement a comprehensive individualized plan of care through an interdisciplinary care team in consultation with the beneficiary, as feasible, identifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided.

(iii) In the management of care, use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

(iv) Provide, on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the individual's consent, for face-to-face encounters for the delivery of health care or care management or care coordination services and be between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff, or contracted plan healthcare providers. A face-for-face encounter must be either in person or through a visual, real-time, interactive telehealth encounter.

(2) MA organizations offering SNPs must also develop and implement the following model of care components to assure an effective care management structure:

(i) Target one of the three SNP populations defined in § 422.2 of this part.

(ii) Have appropriate staff (employed, contracted, or non-contracted) trained on the SNP plan model of care to coordinate and/or deliver all services and benefits.

(iii) Coordinate the delivery of care across healthcare settings, providers, and services to assure continuity of care.

(iv) Coordinate the delivery of specialized benefits and services that meet the needs of the most vulnerable beneficiaries among the three target special needs populations as defined in § 422.2 of this part, including frail/disabled beneficiaries and beneficiaries near the end of life.

(v) Coordinate communication among plan personnel, providers, and beneficiaries.

(3)(i) All MA organizations wishing to offer or continue to offer a SNP will be required to be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval in accordance with CMS guidance.

(ii) As part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care.

(A) Plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals.

(B) Plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval.

(C) If the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC.

(iii) Each element of the model of care of a plan must meet a minimum benchmark score of 50 percent, and a plan's model of care will only be approved if each element of the model of care meets the minimum benchmark.

[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; 73 FR 54248, Sept. 18, 2008; 74 FR 1541, Jan. 12, 2009; 76 FR 21562, Apr. 15, 2011; 76 FR 54634, Sept. 1, 2011; 77 FR 22167, Apr. 12, 2012; 83 FR 16724, Apr. 16, 2018; 86 FR 6094, Jan. 19, 2021; 86 FR 29528, June 2, 2021; 87 FR 22427, Apr. 14, 2022; 87 FR 27894, May 9, 2022; 88 FR 22328, Apr. 12, 2023]

§ 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 for Part A and B benefits only as a mandatory supplemental benefit.

(5) An MA plan may reduce the cost sharing for items and services that are not basic benefits only as a mandatory supplemental benefit (reductions or payment of cost sharing for Part D drugs is not permissible as a Part C supplemental benefit).

(6) An MA plan may offer mandatory supplemental benefits in the following forms:

(i) Reductions in cost sharing through the use of reimbursement, through a debit card or other means, for cost sharing paid for covered benefits. Reimbursements must be limited to the specific plan year.

(ii) Use of a uniform dollar amount as a maximum plan allowance for a package of supplemental benefits, including reductions in cost sharing or coverage of specific items and services, available to enrollees on a uniform basis for enrollee use for any supplemental benefit in the package. Allowance must be limited to the specific plan year.

(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) *Supplemental benefits packaging.* 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.

(e) *Supplemental benefits for certain dual eligible special needs plans.* Subject to CMS approval, fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans that meet minimum performance and quality-based standards may offer additional supplemental benefits, consistent with the requirements of this part, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population provided that the special needs plan—

(1) Operated in the MA contract year prior to the MA contract year for which it is submitting its bid; and

(2) Offers its enrollees such benefits without cost-sharing or additional premium charges.

(f) *Special supplemental benefits for the chronically ill (SSBCI)*—(1) *Requirements*—(i) *Chronically-ill enrollee.* (A) A chronically ill enrollee is an individual enrolled in the MA plan who has one or more comorbid and medically complex chronic conditions that meet all of the following:

(*1*) Is life threatening or significantly limits the overall health or function of the enrollee;

(*2*) Has a high risk of hospitalization of other adverse health outcomes; and

(*3*) Requires intensive care coordination.

(B) CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life threatening or significantly limit the overall health or function of an individual.

(ii) *SSBCI definition.* A special supplemental benefit for the chronically ill (SSBCI) is a supplemental benefit that has, with respect to a chronically ill enrollee, a reasonable expectation of improving or maintaining the health or overall function of the enrollee; an SSBCI that meets the standard in this paragraph (f)(1)(ii) may also include a benefit that is not primarily health related.

(2) *Offering SSBCI.* (i) An MA plan may offer SSBCI to a chronically ill enrollee only as a mandatory supplemental benefit.

(ii) Upon approval by CMS, an MA plan may offer SSBCI that are not uniform for all chronically ill enrollees in the plan.

(iii) An MA plan may consider social determinants of health as a factor to help identify chronically ill enrollees whose health or overall function could be improved or maintained with SSBCI. An MA plan may not use social determinants of health as the sole basis for determining eligibility for SSBCI.

(3) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:

(i) Must have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the definition in paragraph (f)(1)(i) of this section.

(ii) Make information and documentation related to determining enrollee eligibility available to CMS upon request.

(iii) Must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document these criteria.

(iv) Document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request.

[65 FR 40320, June 29, 2000, as amended at 70 FR 4720, Jan. 28, 2005; 77 FR 22167, Apr. 12, 2012; 83 FR 16724, Apr. 16, 2018; 84 FR 15828, Apr. 16, 2019; 85 FR 33903, June 2, 2020; 86 FR 6095, Jan. 19, 2021]

§ 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).

(3) Is pro-rated for enrollments occurring during a beneficiary's initial coverage election period as described at § 422.62(a)(1) of this part or during any other enrollments occurring after January 1.

(e) All MA organizations offering MSA plans must provide enrollees with available information on the cost and quality of services in their service area, and submit to CMS for approval a proposed approach to providing such information.

[63 FR 35077, June 26, 1998, as amended at 70 FR 4720, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 74 FR 1541, Jan. 12, 2009; 75 FR 19805, Apr. 15, 2010]

§ 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 HMO 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 an HMO plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under an HMO plan as an optional supplemental benefit as described in § 422.102(b).

(c) *Ensuring availability and continuity of care.* An MA HMO 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 HMO 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; 75 FR 19805, Apr. 15, 2010]

§ 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 employer-sponsored group 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.

(4) An employer-sponsored group MA plan means MA coverage offered to retirees who are Medicare eligible individuals under employment-based retiree health coverage, as defined in paragraph (d)(5) of this section, approved by CMS as an MA plan.

(5) Employment-based retiree coverage means coverage of health care costs under a group health plan, as defined in paragraph (d)(6) of this section, 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.

(6) 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:

(i) 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 5 U.S.C. 89 (the Federal Employee Health Benefit Plan (FEHBP)).

(ii) 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.

(iii) 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).

(iv) Any of the following plans:

(A) 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.

(B) A health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2).

(C) A health savings account (HSA) as defined in Code section 223.

(D) 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).

[65 FR 40320, June 29, 2000, as amended at 68 FR 50856, Aug. 22, 2003; 70 FR 4721, Jan. 28, 2005; 76 FR 21562, Apr. 15, 2011]

§ 422.107 Requirements for dual eligible special needs plans.

(a) *Definition.* For the purpose of this section, a contract with a State Medicaid agency means a formal written agreement between an MA organization and the State Medicaid agency documenting each entity's roles and responsibilities with regard to dual eligible individuals.

(b) *General rule.* MA organizations seeking to offer a dual eligible special needs plan must have a contract consistent with this section with the State Medicaid agency.

(c) *Minimum contract requirements.* At a minimum, the contract must document—

(1) The MA organization's responsibility to—

(i) Coordinate the delivery of Medicaid benefits for individuals who are eligible for such services; and

(ii) If applicable, provide coverage of Medicaid services, including long-term services and supports and behavioral health services, for individuals eligible for such services.

(2) The category(ies) and criteria for eligibility for dual eligible individuals to be enrolled under the SNP, including as described in sections 1902(a), 1902(f), 1902(p), and 1905 of the Act.

(3) The Medicaid benefits covered under a capitated contract between the State Medicaid agency and the MA organization offering the SNP, the SNP's

parent organization, or another entity that is owned and controlled by the SNP's parent organization.

(4) The cost-sharing protections covered under the SNP.

(5) The identification and sharing of information on Medicaid provider participation.

(6) The verification of an enrollee's Medicaid eligibility.

(7) The service area covered by the SNP.

(8) The contract period for the SNP.

(9) For each dual eligible special needs plan that is an applicable integrated plan as defined in § 422.561, a requirement for the use of the unified appeals and grievance procedures under §§ 422.629 through 422.634, 438.210, 438.400, and 438.402.

(d) *Additional minimum contract requirement.* (1) For any dual eligible special needs plan that is not a fully integrated or highly integrated dual eligible special needs plan, except as specified in paragraph (d)(2) of this section, the contract must also stipulate that, for the purpose of coordinating Medicare and Medicaid-covered services between settings of care, the SNP notifies, or arranges for another entity or entities to notify, the State Medicaid agency, individuals or entities designated by the State Medicaid agency, or both, of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, identified by the State Medicaid agency. The State Medicaid agency must establish the timeframe(s) and method(s) by which notice is provided. In the event that a SNP authorizes another entity or entities to perform this notification, the SNP must retain responsibility for complying with the requirement in this paragraph (d)(1).

(2) For a dual eligible special needs plan that, under the terms of its contract with the State Medicaid agency, only enrolls beneficiaries who are not entitled to full medical assistance under a State plan under title XIX of the Act, paragraph (d)(1) of this section does not apply if the SNP operates under the same parent organization and in the same service area as a dual eligible special needs plan limited to beneficiaries with full medical assistance under a State plan under title XIX of the Act that meets the requirements at paragraph (d)(1) of this section.

(e) *Additional opportunities in certain integrated care programs.* (1) CMS facilitates operationalization as described in paragraphs (e)(2) and (3) of this section if a State Medicaid agency requires MA organizations offering dual eligible special needs plans with exclusively aligned enrollment to do both of the following:

(i) Apply for, and seek CMS approval to establish and maintain, one or more MA contracts that only include one or more dual eligible special needs plans with a service area limited to that State.

(ii) Use required materials that integrate Medicare and Medicaid content, including at a minimum the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory that meets Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 438 of this chapter.

(2) The requirements, processes, and procedures applicable to dual eligible special needs plans and the MA program, including for applications, bids, and contracting procedures under §§ 422.250 through 422.530, remain applicable. Because implementation of the contract provisions described in paragraph (e)(1) of this section may require administrative steps that cannot be completed between reviewing the contract and the start of the plan year, CMS begins good faith work following receipt of a letter from the State Medicaid agency indicating intent to include the provisions described in paragraph (e)(1) of this section in a future contract year and collaborate with CMS on implementation.

(3) When the conditions of paragraph (e)(1) of this section are met—

(i) Following a State request, CMS grants access for State Medicaid agency officials to the Health Plan Management System (HPMS) (or its successor) for purposes of oversight and information-sharing related to the MA contract(s) described in paragraph (e)(1)(i) of this section, as long as State Medicaid agency officials agree to protect the proprietary nature of information

to which the State Medicaid agency may not otherwise have direct access. State access to the Health Plan Management System (or its successor) is subject to compliance with HHS and CMS policies and standards and with applicable laws in the use of HPMS data and the system's functionality. CMS may terminate a State official's access to the Health Plan Management System (or its successor) if any policy is violated or if information is not adequately protected; and

(ii) CMS coordinates with States on program audits, including information-sharing on major audit findings and coordination of audits schedules for the D–SNPs subject to paragraph (e)(1) of this section.

(f) *Enrollee advisory committee.* Any MA organization offering one or more D–SNPs in a State must establish and maintain one or more enrollee advisory committees that serve the D–SNPs offered by the MA organization in that State.

(1) The enrollee advisory committee must include at least a reasonably representative sample of the population enrolled in the dual eligible special needs plan or plans, or other individuals representing those enrollees, and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

(2) The enrollee advisory committee may also advise managed care plans that serve D–SNP enrollees under title XIX of the Act offered by the same parent organization as the MA organization offering the D–SNP.

(g) *Permissible carve-outs of long-term services and supports for FIDE SNPs and HIDE SNPs.* A plan meets the FIDE SNP or HIDE SNP definition at § 422.2, even if its contract with the State Medicaid agency for the provision of services under title XIX of the Act has carve-outs of long-term services and supports, as approved by CMS, that—

(1) Apply primarily to a minority of the beneficiaries eligible to enroll in the dual eligible special needs plan who use long-term services and supports; or

(2) Constitute a small part of the total scope of long-term services and supports provided to the majority of beneficiaries eligible to enroll in the dual eligible special needs plan.

(h) *Permissible carve-outs of behavioral health services for FIDE SNPs and HIDE SNPs.* A plan meets the FIDE SNP or HIDE SNP definition at § 422.2, even if its contract with the State Medicaid agency for the provision of services under title XIX of the Act has carve-outs of behavioral health services, as approved by CMS, that—

(1) Apply primarily to a minority of the beneficiaries eligible to enroll in the dual eligible special needs plan who use behavioral health services; or

(2) Constitute a small part of the total scope of behavioral health services provided to the majority of beneficiaries eligible to enroll in the dual eligible special needs plan.

(i) *Date of Compliance.* (1) Effective January 1, 2010—

(i) MA organizations offering a new dual-eligible SNP must have a State Medicaid agency contract.

(ii) Existing dual-eligible SNPs that do not have a State Medicaid agency contract—

(A) May continue to operate through the 2012 contract year provided they meet all other statutory and regulatory requirements.

(B) May not expand their service areas during contract years 2010 through 2012.

(2) MA organizations offering a dual eligible SNP must comply with paragraphs (c)(9) and (d) of this section beginning January 1, 2021.

[73 FR 54248, Sept. 18, 2008, as amended at 76 FR 21563, Apr. 15, 2011; 84 FR 15828, Apr. 16, 2019; 84 FR 26579, June 7, 2019; 87 FR 27894, May 9, 2022]

§ 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, including reporting, on an ongoing basis, information obtained related to requirements in paragraphs (b)(1) and (b)(2) of this section in accordance with CMS instructions.

(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; 75 FR 19805, Apr. 15, 2010]

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits; coverage of clinical trials and A and B device trials.

(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.

(e) *Clinical trials specified in NCD 310.1.* (1) With the exception specified in paragraph (e)(3) of this section, original Medicare is responsible for coverage of MA enrollees participating in CMS-approved clinical trials to include routine costs, as specified in NCD 310.1, and any coverage for the diagnosis or treatment of complications related to the clinical trial.

(2) MA enrollees are not charged traditional Medicare Part A and B deductibles for clinical trial coverage.

(3) MA plans are responsible for paying the difference between traditional Medicare cost-sharing incurred for qualifying clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services.

(4) An enrollee's in-network cost-sharing portion must be included in the MA plan's maximum out-of-pocket calculation.

(5) MA plans may not require prior authorization for participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial.

(f) *A and B IDE trials.* (1) MA plans are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies that are covered under § 405.211(a) of this chapter.

(2) MA plans are responsible for coverage of CMS-approved Category B devices that are covered under § 405.211(b) of this chapter.

[68 FR 50856, Aug. 22, 2003, as amended at 70 FR 4721, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 88 FR 22329, Apr. 12, 2023]

§ 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.* For coverage before January 1, 2021, 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; 85 FR 33904, June 2, 2020]

§ 422.111 Disclosure requirements.

(a) *Detailed description.* An MA organization must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

(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, by the first day of the annual coordinated election period.

(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) By a dual eligible special needs plan, prior to enrollment, for each prospective enrollee, a comprehensive written statement describing cost sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX.

(iv) 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; each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office; 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 procedures of subpart V of this part.

(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 provide enrollees notice of a termination of a contracted provider, irrespective of whether the termination was for cause or without cause, in accordance with §422.2267(e)(12). The MA organization must make a good faith effort to provide enrollees notice of a for-cause termination of a contracted provider within the timeframes required by this paragraph (e). For all terminations, the MA organization must meet the following requirements:

(1) For contract terminations that involve a primary care or behavioral health provider:

(i) Provide written notice and make one attempt at telephonic notice to those enrollees identified in paragraph (e)(1)(iii) of this section who have not opted out of calls regarding plan business as described in §422.2264(b),

(ii) At least 45 calendar days before the termination effective date, and

(iii) To all enrollees who are currently assigned to that primary care provider and to enrollees who have been patients of that primary care or

behavioral health provider within the past three years.

(2) For contract terminations that involve specialty types other than primary care or behavioral health:

(i) Provide written notice,

(ii) At least 30 calendar days before the termination effective date, and

(iii) To all enrollees who are patients seen on a regular basis by the provider whose contract is terminating. The phrase ''enrollees who are patients seen on a regular basis by the provider whose contract is terminating'' means enrollees who are assigned to, currently receiving care from, or have received care within the past three months from a provider or facility being terminated.

(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.

(g) CMS may require an MA organization to disclose to its enrollees or potential enrollees, the MA organization's performance and contract compliance deficiencies in a manner specified by CMS.

(h) *Provision of specific information.* Each MA organization must have

mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include all of the following:

(1) A toll-free customer service call center that meets all of the following:

(i)(A)Is open during usual business hours.

(B) For coverage beginning on and after January 1, 2022, is open at least from 8:00 a.m. to 8:00 p.m. in all service areas served by the Part C plan, with the following exceptions:

(1) From October 1 through March 31 of the following year, a customer call center may be closed on Thanksgiving Day and Christmas Day so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(2) From April 1 through September 30, a customer call center may be closed any Federal holiday, Saturday, or Sunday, so long as the interactive voice response (IVR) system or similar technology records messages from incoming callers and such messages are returned within one (1) business day.

(ii) Provides customer telephone service in accordance with standard business practices.

(A) For coverage beginning on and after January 1, 2022, limits average hold time to no longer than 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) For coverage beginning on and after January 1, 2022, answers 80 percent of incoming calls within 30 seconds after the interactive voice response (IVR), touch-tone response system, or recorded greeting interaction.

(C) For coverage beginning on and after January 1, 2022, limits the disconnect rate of all incoming calls to no higher than 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii)(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(B) For coverage beginning on and after January 1, 2022, interpreters must be available for 80 percent of incoming calls requiring an interpreter within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

(iv) At a minimum, for coverage beginning on and after January 1, 2022:

(A) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

(B) Connects 80 percent of incoming calls requiring TTY services to a TTY operator within 7 minutes.

(2) An Internet Web site that includes, at a minimum the following:

(i) The information required in paragraph (b) of this section.

(ii) Copies of its evidence of coverage and information (names, addresses, phone numbers, and specialty) on the network of contracted providers. Posting does not relieve the MA organization of its responsibility under paragraph (a) of this section to provide hard copies to enrollees upon request.

(iii) Posting does not relieve the MA organization of its responsibility under paragraph (a) of this section to provide hard copies of the Summary of Benefits to enrollees when CMS determines hard copy delivery of the Summary of Benefits is in the best interest of the beneficiary.

(3) The provision of information in writing, upon request.

(i) *Provision of information required for access to covered services.* MA plans must issue and reissue (as appropriate) member identification cards that enrollees may use to access covered services under the plan. The cards must comply with standards established by CMS.

(j) *Safe disposal of certain prescription drugs.* Information regarding the safe disposal of prescription drugs that are controlled substances and drug takeback programs must be provided in the case of an individual enrolled under

an MA plan who is furnished an in-home health risk assessment on or after January 1, 2022. For purposes of this paragraph (j), a health risk assessment furnished to an individual who is residing in an institutional setting, such as a nursing facility, that has the primary responsibility for the disposal of unused medications, is not considered an in-home health risk assessment. As part of the in-home health risk assessment, the enrollee must be furnished written supporting materials describing how to safely dispose of medications that are controlled substances as well as a verbal summary of the written information as described at paragraphs (j)(1) through (6) of this section when possible. The written information furnished to enrollees about the safe disposal of medications and takeback programs must include the following information for enrollees:

(1) Unused medications should be disposed of as soon as possible.

(2) The U.S. Drug Enforcement Administration (DEA) allows unused prescription medications to be mailed back to pharmacies and other authorized sites using packages made available at such pharmacies or other authorized sites. Include a web link to the information available on the DEA website at *www.deatakeback.com* and the web link to the DEA search engine which enables beneficiaries to identify drug take back sites in their community at the following web address: *https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1*.

(3) Community take back sites are the preferred method of disposing of unused controlled substances.

(4) The location of two or more drug take back sites that are available in the community where the enrollee resides.

(5) Instructions on how to safely dispose of medications in household trash or of cases when a medication can be safely flushed. Include instructions on removing personal identification information when disposing of prescription containers. If applicable, the instructions may also include information on the availability of in-home drug deactivation kits in the enrollee's community.

(6) Include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following web address: *www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html*

(k) *Claims information.* MA organizations 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 benefits are provided under this part.

(1) *Information requirements for the reporting period.* Claims data elements presented on the explanation of benefits must include all of the following for the reporting period:

(i) The descriptor and billing code for the item or service billed by the provider, and the corresponding amount billed.

(ii) The total cost approved by the plan for reimbursement.

(iii) The share of total cost paid for by the plan.

(iv) The share of total cost for which the enrollee is liable.

(2) *Information requirements for year-to-date totals.* Claims data elements presented on the explanation of benefits must include specific year-to-date totals as follows:

(i) The cumulative amount billed by all providers.

(ii) The cumulative total costs approved by the plan.

(iii) The cumulative share of total cost paid for by the plan.

(iv) The cumulative share of total cost for which the enrollee is liable.

(v) The amount an enrollee has incurred toward the MOOP limit, as applicable.

(vi) The amount an enrollee has incurred toward the deductible, as applicable.

(3) *Additional information requirements.* (i) Each explanation of benefits must include clear contact information for enrollee customer service.

(ii) Each explanation of benefits must include instructions on how to report fraud.

(iii) Each EOB that includes a denied claim must clearly identify the denied claim and provide information about

enrollee appeal rights, but the EOB does not replace the notice required by §§ 422.568 and 422.570.

(4) *Reporting cycles for explanation of benefits.* MA organizations must send an explanation of benefits on either a monthly cycle or a quarterly cycle with per-claim notifications.

(i) A monthly explanation of benefits must include all claims processed in the prior month and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the prior month.

(A) The monthly explanation of benefits must be sent before the end of each month that follows the month a claim was filed.

(B) [Reserved]

(ii) A quarterly explanation of benefits must include all claims processed in the quarter and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the quarter; a per-claim notification must include all claims processed in the prior month and, for each claim, the information specified in paragraph (k)(1) of this section as of the last day of the prior month.

(A) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the quarterly explanation of benefits before the end of each month that follows the quarter in which a claim was filed.

(B) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the per-claim notification before the end of each month that follows the month in which a claim was filed.

(5) *Exceptions.* MA organizations are not required to send the explanation of benefits to dual-eligible 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; 73 FR 54220, 54249, Sept. 18, 2008; 75 FR 19805, Apr. 15, 2010; 76 FR 21563, Apr. 15, 2011; 77 FR 22167, Apr. 12, 2012; 80 FR 7959, Feb. 12, 2015; 83 FR 16724, Apr. 16, 2018; 84 FR 15828, Apr. 16, 2019; 86 FR 6095, Jan. 19, 2021; 88 FR 22329, Apr. 12, 2023]

§ 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. The network must include providers that specialize in behavioral health services.

(ii) *Exception*: MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.

(iii) Arrange for and cover any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

(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).

(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 in this paragraph. The MA organization must continuously monitor access to care and member services and must take corrective action as necessary to ensure that appointment wait times in the provider network comply with these standards. The minimum standards for appointment wait times for primary care and behavioral health services are as follows for appointments:

(A) Urgently needed services or emergency—immediately;

(B) Services that are not emergency or urgently needed, but the enrollee requires medical attention—within 7 business days; and

(C) Routine and preventive care—within 30 business days.

(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) *Ensuring equitable access to Medicare Advantage (MA) Services.* Ensure that services are provided in a culturally competent manner and to promote equitable access to all enrollees, including the following:

(i) People with limited English proficiency or reading skills.

(ii) People of ethnic, cultural, racial, or religious minorities.

(iii) People with disabilities.

(iv) People who identify as lesbian, gay, bisexual, or other diverse sexual orientations.

(v) People who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex.

(vi) People living in rural areas and other areas with high levels of deprivation.

(vii) People otherwise adversely affected by persistent poverty or inequality.

(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.

(10) *Prevailing patterns of community health care delivery.* MA plans that meet Medicare access and availability requirements through direct contracting network providers must do so consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. Factors making up community patterns of health care delivery that CMS will use as a benchmark in evaluating a proposed MA plan health care delivery network include, but are not limited to the following:

(i) The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans.

(ii) The prevailing market conditions in the service area of the MA plan. Specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan.

(iii) Whether the service area is comprised of rural or urban areas or some combination of the two.

(iv) Whether the MA plan's proposed provider network meet Medicare time and distance standards for member access to health care providers including specialties.

(v) Other factors that CMS determines are relevant in setting a standard for an acceptable health care delivery network in a particular service area.

(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 behavioral health 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.

(7) With respect to drugs for which payment as so prescribed and dispensed or administered to an individual may be available under Part A or Part B, or under Part D, MA–PD plans must coordinate all benefits administered by the plan and—

(i) Establish and maintain a process to ensure timely and accurate point-of-sale transactions; and

(ii) Issue the determination and authorize or provide the benefit under Part A or Part B or as a benefit under Part D as expeditiously as the enrollee's health condition requires, in accordance with the requirements of subpart M of this part and subpart M of part 423 of this chapter, as appropriate, when a party requests a coverage determination.

(8)(i) With respect to basic benefits, policies for using prior authorization that at a minimum include that for enrollees undergoing an active course of treatment—

(A) Approval of a prior authorization request for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care, in accordance with applicable coverage criteria, the individual patient's medical history, and the treating provider's recommendation; and

(B) A minimum 90-day transition period for any active course(s) of treatment when an enrollee has enrolled in an MA plan after starting a course of treatment, even if the service is furnished by an out-of-network provider. This includes enrollees new to a plan and enrollees new to Medicare. The MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

(ii) For purposes of this paragraph (b)(8), the following definitions apply:

(A) *Course of treatment* means as a prescribed order or ordered course of treatment for a specific individual with a specific condition is outlined and decided upon ahead of time with the patient and provider. A course of treatment may but is not required to be part of a treatment plan.

(B) *Active course of treatment* means a course of treatment in which a patient is actively seeing the provider and following the course of treatment.

(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; 75 FR 19805, Apr. 15, 2010; 76 FR 21563, Apr. 15, 2011; 80 FR 7959, Feb. 12, 2015; 88 FR 22330, Apr. 12, 2023]

§ 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, mental or physical, 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 in this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or 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 dollar limit on emergency services costs for enrollees that is the lower of—

(A) The cost sharing established by the MA plan if the emergency services were provided through the MA organization; or

(B) A maximum cost sharing limit permitted per visit that corresponds to the MA plan MOOP limit as follows:

(*1*) For 2023, $95 for a mandatory MOOP limit, $110 for an intermediate MOOP limit, and $125 for a lower MOOP limit.

(*2*) For 2024, $100 for a mandatory MOOP limit, $120 for an intermediate MOOP limit, and $135 for a lower MOOP limit.

(*3*) For 2025, $110 for a mandatory MOOP limit, $125 for an intermediate MOOP limit, and $140 for a lower MOOP limit.

(*4*) For 2026 and subsequent years, $115 for a mandatory MOOP limit, $130 for an intermediate MOOP limit, and $150 for a lower MOOP limit.

(vi) For each year beginning on or after January 1, 2023, with a cost sharing limit on urgently needed services that does not exceed the limits specified for professional services in § 422.100(f)(6)(iii).

(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 pre-approved 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; 76 FR 21563, Apr. 15, 2011; 80 FR 7959, Feb. 12, 2015; 87 FR 22428, Apr. 14, 2022; 88 FR 22330, Apr. 12, 2023]

§ 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) Subject to paragraphs (a)(3) and (a)(4) of this section, 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) Subject to paragraph (A) of section (a)(2)(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

(A) For plan year 2010 and subsequent plan years, contracts or agreements with a sufficient number and range of providers to meet the access standards described in section 1852(d)(1) of the Act.

(B) [Reserved]

(iii) A combination of paragraphs (a)(2)(i) and (a)(2)(ii) of this section.

(3) For plan year 2011 and subsequent plan years, an MA organization that offers an MA private fee-for-service plan (other than a plan described in section 1857(i)(1) or (2) of the Act) that is operating in a network area (as defined in paragraph (a)(3)(i) of this section) meets the requirement in paragraph (a)(1) of this section only if the MA organization has contracts or agreements with providers in accordance with paragraph (a)(2)(ii)(A) of this section.

(i) Network area is defined, for a given plan year, as the area that the Secretary identifies in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year as having at least 2 network-based plans (as defined in paragraph (a)(3)(ii) of this section) with enrollment as of the first day of the year in which the announcement is made.

(ii) Network-based plan is defined as a coordinated care plan as described in § 422.4(a)(1)(ii), a network-based MSA plan, or a section 1876 reasonable cost plan. A network-based plan excludes a

MA regional plan that meets access requirements substantially through the authority of § 422.112(a)(1)(ii) instead of written contracts.

(4) For plan year 2011 and subsequent plan years, an MA organization that offers an MA private fee-for-service plan that is described in section 1857(i)(1) or (2) of the Act meets the requirement in paragraph (a)(1) of this section only if the MA organization has contracts or agreements with providers in accordance with paragraph (a)(2)(ii)(A) 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; 73 FR 54249, Sept. 18, 2008]

§ 422.116 Network adequacy.

(a) *General rules*—(1) *Access.* (i) A network-based MA plan, as described in § 422.2 but not including MSA plans, must demonstrate that it has an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards described in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1) and by meeting the standard in paragraph (a)(2) of this section. When required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year.

(ii) Beginning with contract year 2024, an applicant for a new or expanding service area must demonstrate compliance with this section as part of its application for a new or expanding service area and CMS may deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

(2) *Standards.* An MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type.

(i) Each contract provider type must be within maximum time and distance of at least one beneficiary (in the MA Medicare Sample Census) in order to count toward the minimum number.

(ii) The minimum number criteria and the time and distance criteria vary by the county type.

(3) *Applicability of MA network adequacy criteria.* (i) The following providers and facility types do not count toward meeting network adequacy criteria:

(A) Specialized, long-term care, and pediatric/children's hospitals.

(B) Providers that are only available in a residential facility.

(C) Providers and facilities contracted with the organization only for its commercial, Medicaid, or other products.

(ii) [Reserved]

(4) *Annual updates by CMS.* CMS annually updates and makes the following available:

(i) A Health Service Delivery (HSD) Reference file that identifies the following:

(A) All minimum provider and facility number requirements.

(B) All provider and facility time and distance standards.

(C) Ratios established in paragraph (e) of this section in advance of network reviews for the applicable year.

(ii) A Provider Supply file that lists available providers and facilities and their corresponding office locations and specialty types.

(A) The Provider Supply file is updated annually based on information in the Integrated Data Repository (IDR), which has comprehensive claims data, and information from public sources.

(B) CMS may also update the Provider Supply file based on findings from validation of provider information submitted on Exception Requests

to reflect changes in the supply of health care providers and facilities.

(b) *Provider and facility-specialty types.* The provider and facility-specialty types to which the network adequacy evaluation under this section applies are specified in this paragraph (b).

(1) *Provider-specialty types.* The provider-specialty types are as follows:

(i) Primary Care.
(ii) Allergy and Immunology.
(iii) Cardiology.
(iv) Chiropractor.
(v) Dermatology.
(vi) Endocrinology.
(vii) ENT/Otolaryngology.
(viii) Gastroenterology.
(ix) General Surgery.
(x) Gynecology, OB/GYN.
(xi) Infectious Diseases.
(xii) Nephrology.
(xiii) Neurology.
(xiv) Neurosurgery.
(xv) Oncology—Medical, Surgical.
(xvi) Oncology—Radiation/Radiation Oncology.
(xvii) Ophthalmology.
(xviii) Orthopedic Surgery.
(xix) Physiatry, Rehabilitative Medicine.
(xx) Plastic Surgery.
(xxi) Podiatry.
(xxii) Psychiatry.
(xxiii) Pulmonology.
(xxiv) Rheumatology.
(xxv) Urology.
(xxvi) Vascular Surgery.
(xxvii) Cardiothoracic Surgery.
(xxviii) Clinical Psychology.
(xxix) Clinical Social Work.

(2) *Facility-specialty types.* The facility specialty types are as follows:

(i) Acute Inpatient Hospitals.
(ii) Cardiac Surgery Program.
(iii) Cardiac Catheterization Services.
(iv) Critical Care Services—Intensive Care Units (ICU).
(v) Surgical Services (Outpatient or ASC).
(vi) Skilled Nursing Facilities.
(vii) Diagnostic Radiology.
(viii) Mammography.
(ix) Physical Therapy.
(x) Occupational Therapy.
(xi) Speech Therapy.
(xii) Inpatient Psychiatric Facility Services.
(xiii) Outpatient Infusion/Chemotherapy.

(3) *Removal of a provider or facility-specialty type.* CMS may remove a specialty or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file.

(c) *County type designations.* Counties are designated as a specific type using the following population size and density parameters:

(1) *Large metro.* A large metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 1,000 persons per square mile.

(ii) A population size greater than or equal to 500,000 and less than or equal to 999,999 persons with a population density greater than or equal to 1,500 persons per square mile.

(iii) Any population size with a population density of greater than or equal to 5,000 persons per square mile.

(2) *Metro.* A metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 999.9 persons per square mile.

(ii) A population size greater than or equal to 500,000 persons and less than or equal to 999,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 1,499.9 persons per square mile.

(iii) A population size greater than or equal to 200,000 persons and less than or equal to 499,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 4,999.9 persons per square mile.

(iv) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal to 100 persons per square mile and less than or equal to 4999.9 persons per square mile.

(v) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 1,000 persons per square mile and less than or equal to 4999.9 persons per square mile.

(3) *Micro*. A micro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 99.9 persons per square mile.

(ii) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 50 persons per square mile and less than 999.9 persons per square mile.

(4) *Rural*. A rural designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density of greater than or equal to 10 persons per square mile and less than or equal to 49.9 persons per square mile.

(ii) A population size less than 10,000 persons with a population density greater than or equal 50 persons per square mile and less than or equal to 999.9 persons per square mile.

(5) *Counties with extreme access considerations (CEAC)*. For any population size with a population density of less than 10 persons per square mile.

(d) *Maximum time and distance standards*—(1) *General rule*. CMS determines and annually publishes maximum time and distance standards for each combination of provider or facility specialty type and each county type in accordance with paragraphs (d)(2) and (3) of this section.

(i) Time and distance metrics measure the relationship between the approximate locations of beneficiaries and the locations of the network providers and facilities.

(ii) [Reserved]

(2) *By county designation*. The following base maximum time (in minutes) and distance (in miles) standards apply for each county type designation, unless modified through customization as described in paragraph (d)(3) of this section.

TABLE 1 TO PARAGRAPH (d)(2)

Provider/Facility type	Large metro		Metro		Micro		Rural		CEAC	
	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance
Primary Care	10	5	15	10	30	20	40	30	70	60
Allergy and Immunology	30	15	45	30	80	60	90	75	125	110
Cardiology	20	10	30	20	50	35	75	60	95	85
Chiropractor	30	15	45	30	80	60	90	75	125	110
Clinical Psychology	20	10	45	30	60	45	75	60	145	130
Dermatology	20	10	45	30	60	45	75	60	110	100
Endocrinology	30	15	60	40	100	75	110	90	145	130
ENT/Otolaryngology	30	15	45	30	80	60	90	75	125	110
Gastroenterology	20	10	45	30	60	45	75	60	110	100
General Surgery	20	10	30	20	50	35	75	60	95	85
Gynecology, OB/GYN	30	15	45	30	80	60	90	75	125	110
Infectious Diseases	30	15	60	40	100	75	110	90	145	130
Licensed Clinical Social Work	20	10	30	20	50	35	75	60	125	110
Nephrology	30	15	45	30	80	60	90	75	125	110
Neurology	20	10	45	30	60	45	75	60	110	100
Neurosurgery	30	15	60	40	100	75	110	90	145	130
Oncology—Medical, Surgical	20	10	45	30	60	45	75	60	110	100
Oncology—Radiation/Radiation Oncology	30	15	60	40	100	75	110	90	145	130
Ophthalmology	20	10	30	20	50	35	75	60	95	85
Orthopedic Surgery	20	10	30	20	50	35	75	60	95	85
Physiatry, Rehabilitative Medicine	30	15	45	30	80	60	90	75	125	110
Plastic Surgery	30	15	60	40	100	75	110	90	145	130
Podiatry	20	10	45	30	60	45	75	60	110	100
Psychiatry	20	10	45	30	60	45	75	60	110	100
Pulmonology	20	10	45	30	60	45	75	60	110	100
Rheumatology	30	15	60	40	100	75	110	90	145	130
Urology	20	10	45	30	60	45	75	60	110	100
Vascular Surgery	30	15	60	40	100	75	110	90	145	130
Cardiothoracic Surgery	30	15	60	40	100	75	110	90	145	130
Acute Inpatient Hospitals	20	10	45	30	80	60	75	60	110	100
Cardiac Surgery Program	30	15	60	40	160	120	145	120	155	140

Cardiac Catheterization Services	30	15	60	40	160	120	145	120	155	140
Critical Care Services—Intensive Care Units (ICU)	20	10	45	30	160	120	145	120	155	140
Surgical Services (Outpatient or ASC)	20	10	45	30	80	60	75	60	110	100
Skilled Nursing Facilities	20	10	45	30	80	60	75	60	95	85
Diagnostic Radiology	20	10	45	30	80	60	75	60	110	100
Mammography	20	10	45	30	80	60	75	60	110	100
Physical Therapy	20	10	45	30	80	60	75	60	110	100
Occupational Therapy	20	10	45	30	80	60	75	60	110	100
Speech Therapy	20	10	45	30	80	60	75	60	110	100
Inpatient Psychiatric Facility Services	30	15	70	45	100	75	90	75	155	140
Outpatient Infusion/Chemotherapy	20	10	45	30	80	60	75	60	110	100

(3) *By customization.* When necessary due to utilization or supply patterns, CMS may set maximum time and distance standards for provider or facility types for specific counties by customization in accordance with the following rules:

(i) CMS maps provider location data from the Provider Supply file against its MA Medicare Sample Census (which provides MA enrollee population distribution data) or uses claims data to identify the distances beneficiaries travel according to the usual patterns of care for the county.

(ii) CMS identifies the distance at which 90 percent of the population would have access to at least one provider or facility in the applicable specialty type.

(iii) The resulting distance is then rounded up to the next multiple of 5, and a multiplier specific to the county designation is applied to determine the analogous maximum time.

(iv) Customization may only be used to increase the base time and distance standards specified in paragraph (d)(2) of this section and may not be used to decrease the base time and distance standards.

(4) *Percentage of beneficiaries residing within maximum time and distance standards.* MA plans must ensure both of the following:

(i) At least 85 percent of the beneficiaries residing in micro, rural, or CEAC counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(ii) At least 90 percent of the beneficiaries residing in large metro and metro counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(5) *MA telehealth providers.* An MA plan receives a 10 percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the applicable provider specialty type and county when the plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted networks for the following provider specialty types:

(i) Dermatology.

(ii) Psychiatry.

(iii) Cardiology.

(iv) Neurology.

(v) Otolaryngology.

(vi) Ophthalmology.

(vii) Allergy and Immunology.

(viii) Nephrology.

(ix) Primary Care.

(x) Gynecology/OB/GYN.

(xi) Endocrinology.

(xii) Infectious Diseases.

(xiii) Clinical Psychology.

(xiv)–(xxiii) [Reserved]

(xxiv) Clinical Social Work.

(6) *State Certificate of Need (CON) laws.* In a State with CON laws, or other state imposed anti-competitive restrictions that limit the number of providers or facilities in the State or a county in the State, CMS will award the MA organization a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected providers and facilities in paragraph (b) of this section or, when necessary due to utilization or supply patterns, customize the base time and distance standards.

(7) *New or expanding service area applicants.* Beginning with contract year 2024, an applicant for a new or expanding service area receives a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. In addition, applicants may use a Letter of Intent (LOI), signed by both the MA organization (MAO) and the provider or facility with which the MAO has started or intends to negotiate, in lieu of a signed contract at the time of application and for the duration of the application review, to meet network standards. As part of the network adequacy review process, applicants must notify CMS of their use of LOIs to meet network standards in lieu of a signed contract and submit copies upon request and in the form and manner directed by CMS. At the beginning of the applicable contract year, the credit and the use of LOIs no longer apply and if the application is approved, the MA organization must be

in full compliance with this section, including having signed contracts with the provider or facility.

(e) *Minimum number standard.* CMS annually determines the minimum number standard for each provider and facility-specialty type as follows:

(1) *General rule.* The provider or facility must—

(i) Be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number standard (requirement); and

(ii) Not be a telehealth-only provider.

(2) *Minimum number requirement for provider and facility-specialty types.* The minimum number for provider and facility-specialty types are as follows:

(i) For provider-specialty types described in paragraph (b)(1) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(ii) For facility-specialty types described in paragraph (b)(2)(i) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(iii) For facility-specialty types described in paragraphs (b)(2)(ii) through (xiv) of this section, the minimum requirement number is 1.

(3) *Determination of the minimum number of for certain provider and facility-specialty types.* For specialty types in paragraphs (b)(1) and (b)(2)(i) of this section, CMS multiplies the minimum ratio by the number of beneficiaries required to cover, divides the resulting product by 1,000, and rounds it up to the next whole number.

(i)(A) The minimum ratio for provider specialty types represents the minimum number of providers per 1,000 beneficiaries.

(B) The minimum ratio for facility specialty type specified in paragraph (b)(2)(i) of this section (acute inpatient hospital) represents the minimum number of beds per 1,000 beneficiaries.

(C) The minimum ratios are as follows:

TABLE 2 TO PARAGRAPH (E)(3)(i)(C)

Minimum ratio	Large metro	Metro	Micro	Rural	CEAC
Primary Care	1.67	1.67	1.42	1.42	1.42
Allergy and Immunology	0.05	0.05	0.04	0.04	0.04
Cardiology	0.27	0.27	0.23	0.23	0.23
Chiropractor	0.10	0.10	0.09	0.09	0.09
Clinical Psychology	0.15	0.15	0.13	0.13	0.13
Clinical Social Work	0.25	0.25	0.22	0.22	0.22
Dermatology	0.16	0.16	0.14	0.14	0.14
Endocrinology	0.04	0.04	0.03	0.03	0.03
ENT/Otolaryngology	0.06	0.06	0.05	0.05	0.05
Gastroenterology	0.12	0.12	0.10	0.10	0.10
General Surgery	0.28	0.28	0.24	0.24	0.24
Gynecology, OB/GYN	0.04	0.04	0.03	0.03	0.03
Infectious Diseases	0.03	0.03	0.03	0.03	0.03
Nephrology	0.09	0.09	0.08	0.08	0.08
Neurology	0.12	0.12	0.10	0.10	0.10
Neurosurgery	0.01	0.01	0.01	0.01	0.01
Oncology—Medical, Surgical	0.19	0.19	0.16	0.16	0.16
Oncology—Radiation/Radiation Oncology	0.06	0.06	0.05	0.05	0.05
Ophthalmology	0.24	0.24	0.20	0.20	0.20
Orthopedic Surgery	0.20	0.20	0.17	0.17	0.17
Physiatry, Rehabilitative Medicine	0.04	0.04	0.03	0.03	0.03
Plastic Surgery	0.01	0.01	0.01	0.01	0.01
Podiatry	0.19	0.19	0.16	0.16	0.16
Psychiatry	0.14	0.14	0.12	0.12	0.12
Pulmonology	0.13	0.13	0.11	0.11	0.11
Rheumatology	0.07	0.07	0.06	0.06	0.06
Urology	0.12	0.12	0.10	0.10	0.10
Vascular Surgery	0.02	0.02	0.02	0.02	0.02
Cardiothoracic Surgery	0.01	0.01	0.01	0.01	0.01
Acute Inpatient Hospitals	12.2	12.2	12.2	12.2	12.2

(ii)(A) *Number of beneficiaries required to cover. (1)* The number of beneficiaries required to cover is calculated by multiplying the 95th percentile base population ratio by the total number of

Medicare beneficiaries residing in a county.

(*2*) CMS uses its MA State/County Penetration data to calculate the total number of beneficiaries residing in a county.

(B) *95th percentile base population ratio.* (*1*) The 95th percentile base population ratio is:

(*i*) Calculated annually for each county type and varies over time as MA market penetration and plan enrollment change across markets; and

(*ii*) Represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95 percent of plans have enrollment lower than this level).

(*2*) CMS calculates the 95th percentile base population ratio as follows:

(*i*) Uses its most recent List of PFFS Network Counties to exclude any private-fee-for-service (PFFS) plans in non-networked counties from the calculation at the county-type level.

(*ii*) Uses its most recent MA State/County Penetration data to determine the number of eligible Medicare beneficiaries in each county.

(*iii*) Uses its Monthly MA Enrollment By State/County/Contract data to determine enrollment at the contract ID and county level, including only enrollment in regional preferred provider organization (RPPO), local preferred provider organization (LPPO), HMO, HMO/provider sponsored organization (POS), healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types.

(*iv*) Calculates penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county.

(*v*) Groups counties by county designation to determine the 95th percentile of penetration among MA plans for each county type.

(f) *Exception requests.* (1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when both of the following occur:

(i) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type.

(ii) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

(2) In evaluating exception requests, CMS considers whether—

(i) The current access to providers and facilities is different from the HSD reference and Provider Supply files for the year;

(ii) There are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and

(iii) Approval of the exception is in the best interests of beneficiaries.

[85 FR 33904, June 2, 2020, as amended at 87 FR 27895, May 9, 2022; 88 FR 22330, Apr. 12, 2023]

§ 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]

§ 422.119 Access to and exchange of health data and plan information.

(a) *Application Programming Interface to support MA enrollees.* A Medicare Advantage (MA) organization must implement and maintain a standards-based Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of a current individual MA enrollee or the enrollee's personal representative, data specified in paragraph (b) of this section through the use of common technologies and without special effort from the enrollee.

(b) *Accessible content.* (1) An MA organization must make the following information accessible to its current enrollees or the enrollee's personal representative through the API described in paragraph (a) of this section:

(i) Data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and enrollee cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;

(ii) Encounter data from capitated providers, no later than one (1) business day after data concerning the encounter is received by the MA organization; and

(iii) Clinical data, including laboratory results, if the MA organization maintains any such data, no later than one (1) business day after the data is received by the MA organization.

(2) In addition to the information specified in paragraph (b)(1) of this section, an MA organization that offers an MA–PD plan must make the following information accessible to its enrollees through the API described in paragraph (a) of this section:

(i) Data concerning adjudicated claims for covered Part D drugs, including remittances and enrollee cost-sharing, no later than one (1) business day after a claim is adjudicated; and,

(ii) Formulary data that includes covered Part D drugs, and any tiered formulary structure or utilization management procedure which pertains to those drugs.

(c) *Technical requirements.* An MA organization implementing an API under paragraph (a) of this section:

(1) Must implement, maintain, and use API technology conformant with 45 CFR 170.215;

(2) Must conduct routine testing and monitoring, and update as appropriate, to ensure the API functions properly, including assessments to verify that the API is fully and successfully implementing privacy and security features such as, but not limited to, those required to comply with HIPAA privacy and security requirements in 45 CFR parts 160 and 164, 42 CFR parts 2 and 3, and other applicable law protecting the privacy and security of individually identifiable data;

(3) Must comply with the content and vocabulary standard requirements in paragraphs (c)(3)(i) and (ii) of this section, as applicable to the data type or data element, unless alternate standards are required by other applicable law:

(i) Content and vocabulary standards at 45 CFR 170.213 where such standards are applicable to the data type or element, as appropriate; and

(ii) Content and vocabulary standards at 45 CFR part 162 and § 423.160 of this chapter where required by law or where such standards are applicable to the data type or element, as appropriate.

(4) May use an updated version of any standard or all standards required under paragraph (c)(1) or (3) of this section, where:

(i) Use of the updated version of the standard is required by other applicable law; or

(ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:

(A) For content and vocabulary standards other than those at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of this section or 45 CFR part 170;

(B) For standards at 45 CFR 170.213 and 45 CFR 170.215, the National Coordinator has approved the updated version for use in the ONC Health IT Certification Program; and

(C) Use of the updated version of a standard does not disrupt an end user's ability to access the data described in paragraph (b) of this section through

the API described in paragraph (a) of this section.

(d) *Documentation requirements for APIs.* For each API implemented in accordance with paragraph (a) of this section, an MA organization must make publicly accessible, by posting directly on its website or via publicly accessible hyperlink(s), complete accompanying documentation that contains, at a minimum the information listed in this paragraph. For the purposes of this section, ''publicly accessible'' means that any person using commonly available technology to browse the internet could access the information without any preconditions or additional steps, such as a fee for access to the documentation; a requirement to receive a copy of the material via email; a requirement to register or create an account to receive the documentation; or a requirement to read promotional material or agree to receive future communications from the organization making the documentation available;

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

(2) The software components and configurations an application must use in order to successfully interact with the API and process its response(s); and

(3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

(e) *Denial or discontinuation of access to the API.* An MA organization may deny or discontinue any third party application's connection to the API required under paragraph (a) of this section if the MA organization:

(1) Reasonably determines, consistent with its security risk analysis under 45 CFR part 164 subpart C, that allowing an application to connect or remain connected to the API would present an unacceptable level of risk to the security of protected health information on the MA organization's systems; and

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which enrollees seek to access their electronic health information, as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

(f) *Coordination among payers.* (1) An MA organization must maintain a process for the electronic exchange of, at a minimum, the data classes and elements included in the content standard adopted at 45 CFR 170.213. Such information received by an MA organization must be incorporated into the MA organization's records about the current enrollee. With the approval and at the direction of a current or former enrollee or the enrollee's personal representative, the MA organization must:

(i) Receive all such data for a current enrollee from any other payer that has provided coverage to the enrollee within the preceding 5 years;

(ii) At any time an enrollee is currently enrolled in the MA plan and up to 5 years after disenrollment, send all such data to any other payer that currently covers the enrollee or a payer the enrollee or the enrollee's personal representative specifically requests receive the data; and

(iii) Send data received from another payer under this paragraph (f) in the electronic form and format it was received.

(2) [Reserved]

(g) *Enrollee resources regarding privacy and security.* An MA organization must provide in an easily accessible location on its public website and through other appropriate mechanisms through which it ordinarily communicates with current and former enrollees seeking to access their health information held by the MA organization, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:

(1) General information on steps the individual may consider taking to help protect the privacy and security of their health information including factors to consider in selecting an application including secondary uses of data, and the importance of understanding the security and privacy practices of

any application to which they will entrust their health information; and

(2) An overview of which types of organizations or individuals are and are not likely to be HIPAA covered entities, the oversight responsibilities of the Office for Civil Rights (OCR) and the Federal Trade Commission (FTC), and how to submit a complaint to:

(i) The HHS Office for Civil Rights (OCR); and

(ii) The Federal Trade Commission (FTC).

(h) *Applicability.* (1) An MA organization must comply with the requirements in paragraphs (a) through (e) and (g) of this section beginning January 1, 2021, and with the requirements in paragraph (f) beginning January 1, 2022 with regard to data:

(i) With a date of service on or after January 1, 2016; and

(ii) That are maintained by the MA organization.

(2) [Reserved]

[85 FR 25632, May 1, 2020]

§ 422.120 Access to published provider directory information.

(a) An MA organization must implement and maintain a publicly accessible, standards-based Application Programming Interface (API) that is conformant with the technical requirements at § 422.119(c), excluding the security protocols related to user authentication and authorization and any other protocols that restrict the availability of this information to particular persons or organizations, the documentation requirements at § 422.119(d), and is accessible via a public-facing digital endpoint on the MA organization's website.

(b) The API must provide a complete and accurate directory of—

(1) The MA plan's network of contracted providers, including names, addresses, phone numbers, and specialties, updated no later than 30 calendar days after the MA organizations receives provider directory information or updates to provider directory information; and

(2) For an MA organization that offers an MA–PD plan, the MA–PD's pharmacy directory, including the pharmacy name, address, phone number, number of pharmacies in the network, and mix (specifically the type of pharmacy, such as ''retail pharmacy'') updated no later than 30 calendar days after the MA organization receives pharmacy directory information or updates to pharmacy directory information.

(c) This section is applicable beginning January 1, 2021.

[85 FR 25633, May 1, 2020]

§ 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]

§ 422.134 Reward and incentive programs.

(a) *Definitions.* As used in this section, the following definitions are applicable:

Incentive item means the same things as reward item.

Incentive(s) program, *reward(s) program*, and *R&I program* mean the same thing as rewards and incentives program.

Incentive(s), *R&I*, and *rewards and incentives* mean the same things as reward(s).

Qualifying individual in the context of a plan-covered health benefit means any plan enrollee who would qualify for coverage of the benefit. In the context of a non-plan-covered health benefit, qualifying individual means any plan enrollee.

Reward and incentive program is a program offered by an MA plan to qualifying individuals to voluntarily perform specified target activities in exchange for reward items.

Reward item (or incentive item) means the item furnished to a qualifying individual who performs a target activity as specified by the plan in the reward program.

Target activity means the activity for which the reward is provided to the qualifying individual by the MA plan.

(b) *Offering an R&I program.* An MA plan may offer R&I program(s) consistent with the requirements of this section.

(c) *Target activities.* (1) A target activity in an R&I program must meet all of the following:

(i) Directly involve the qualifying individual and performance by the qualifying individual.

(ii) Be specified, in detail, as to the level of completion needed in order to qualify for the reward item.

(iii) Be health-related by doing at least one of the following:

(A) Promoting improved health.

(B) Preventing injuries and illness,

(C) Promoting the efficient use of health care resources.

(iv) Uniformly offer any qualifying individual the opportunity to participate in the target activity.

(v) Be provided with accommodations consistent with the goal of the target

activity to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity.

(2) The target activity in an R&I program must not do any of the following:

(i) Be related to Part D benefits.

(ii) Discriminate against enrollees. To ensure that anti-discrimination requirements are met, an MA organization, in providing a rewards and incentives program, must comply with paragraph (g)(1) of this section and must not design a program based on the achievement of a health status measurement.

(d) *Reward items.* (1) The reward item for a target activity must meet all of the following:

(i) Be offered identically to any qualifying individual who performs the target activity.

(ii) Be a direct tangible benefit to the qualifying individual who performs the target activity.

(iii) Be provided, to the enrollee, such as through transfer of ownership or delivery, for a target activity completed in the contract year during which this R&I program was offered, regardless if the enrollee is likely to use the reward item after the contract year.

(2) The reward item for a target activity must not:

(i) Be offered in the form of cash, cash equivalents, or other monetary rebates (including reduced cost sharing or premiums). An item is classified as a cash equivalent if it either:

(A) Is convertible to cash (such as a check); or

(B) Can be used like cash (such as a general purpose debit card).

(ii) Have a value that exceeds the value of the target activity itself.

(iii) Involve elements of chance.

(3) Permissible reward items for a target activity may be reward items that:

(i) Consist of ''points'' or ''tokens'' that can be used to acquire tangible items.

(ii) Are offered in the form of a gift card that can be redeemed only at specific retailers or retail chains or for a specific category of items or services.

(e) *Marketing and communication requirements.* An MA organization that offers an R&I program must comply with all marketing and communications requirements in subpart V of this part.

(f) *R&I disclosure.* MA organization must make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

(g) *Miscellaneous.* (1) The MA organization's reward and incentive program must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries. Additionally, all MA program anti-discrimination prohibitions continue to apply. The R&I program may not discriminate against enrollees based on race, color, national origin, including limited English proficiency, sex, age, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty, health status, or other prohibited basis.

(2) Failure to comply with R&I program requirements may result in a violation of one or more of the basis for sanction at § 422.752(a).

(3) The reward and incentive program is classified as a non-benefit expense in the plan bid.

(i) If offering a reward and incentive program, the MA organization must include all costs associated with the reward and incentive program as an administrative cost and non-benefit expense in the bid for the year in which the reward and incentive program operates.

(ii) Disputes on rewards and incentives must be treated as a grievance under § 422.564.

[86 FR 6096, Jan. 19, 2021]

§ 422.135 Additional telehealth benefits.

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

Additional telehealth benefits means services:

(1) For which benefits are available under Medicare Part B but which are

not payable under section 1834(m) of the Act; and

(2) That have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee.

Electronic exchange means electronic information and telecommunications technology.

(b) *General rule.* An MA plan may treat additional telehealth benefits as basic benefits covered under the original Medicare fee-for-service program for purposes of this part 422 provided that the requirements of this section are met. If the MA plan fails to comply with the requirements of this section, then the MA plan may not treat the benefits provided through electronic exchange as additional telehealth benefits, but may treat them as supplemental benefits as described in § 422.102, subject to CMS approval.

(c) *Requirements.* An MA plan furnishing additional telehealth benefits must:

(1) Furnish in-person access to the specified Part B service(s) at the election of the enrollee.

(2) Advise each enrollee that the enrollee may receive the specified Part B service(s) through an in-person visit or through electronic exchange.

(3) Comply with the provider selection and credentialing requirements provided in § 422.204, and, when providing additional telehealth benefits, ensure through its contract with the provider that the provider meet and comply with applicable State licensing requirements and other applicable laws for the State in which the enrollee is located and receiving the service.

(4) Make information about coverage of additional telehealth benefits available to CMS upon request. Information may include, but is not limited to, statistics on use or cost, manner(s) or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements of this section.

(d) *Requirement to use contracted providers.* An MA plan furnishing additional telehealth benefits may only do so using contracted providers. Coverage of benefits furnished by a non-contracted provider through electronic exchange may only be covered as a supplemental benefit.

(e) *Bidding.* An MA plan that fully complies with this section may include additional telehealth benefits in its bid for basic benefits in accordance with § 422.254.

(f) *Cost sharing.* MA plans offering additional telehealth benefits may maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange.

[84 FR 15829, Apr. 16, 2019]

§ 422.136 Medicare Advantage (MA) and step therapy for Part B drugs.

(a) *General.* If an MA plan implements a step therapy program to control the utilization of Part B-covered drugs, the MA organization must—

(1) Apply step therapy only to new administrations of Part B drugs, using at least a 365 day lookback period;

(2) Establish policies and procedures to educate and inform health care providers and enrollees concerning its step therapy policies.

(3) Prior to implementation of a step therapy program, ensure that the step therapy program has been reviewed and approved by the MA organization's pharmacy and therapeutic (P&T) committee.

(b) *Step therapy and pharmacy and therapeutic committee requirements.* An MA plan must establish a P&T committee prior to implementing any step therapy program. An MA plan must use a P&T committee to review and approve step therapy programs used in connection with Part B drugs. To meet this requirement, a MA–PD plan may utilize an existing Part D P&T committee established for purposes of administration of the Part D benefit under part 423 of this chapter and an MA plan may utilize an existing Part D P&T committee established by an MA–PD plan operated under the same contract as the MA plan. The P&T committee must—

(1) Include a majority of members who are practicing physicians or practicing pharmacists.

(2) Include at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to—

(i) The MA organization and MA plan; and

(ii) Pharmaceutical manufacturers.

(3) Include at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(4) Clearly articulate and document processes to determine that the requirements under paragraphs (b)(1) through (3) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(5) Base 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.

(6) Consider whether the inclusion of a particular Part B drug in a step therapy program has any therapeutic advantages in terms of safety and efficacy.

(7) Review policies that guide exceptions and other step therapy processes.

(8) Evaluate and analyze treatment protocols and procedures related to the plan's step therapy policies at least annually consistent with written policy guidelines and other CMS instructions.

(9) Document in writing its decisions regarding the development and revision of step therapy activities and make this documentation available to CMS upon request.

(10) Review and approve all step therapy criteria applied to each covered Part B drug.

(11) Meet other requirements consistent with written policy guidelines and other CMS instructions.

(c) *Off-label drug requirement.* An MA plan may include a drug supported only by an off-label indication in step therapy protocols only if the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices.

(d) *Non-covered drugs.* A step therapy program must not include as a component of a step therapy protocol or other condition or requirement any drugs not covered by the applicable MA plan as a Part B drug or, in the case of an MA–PD plan, a Part D drug.

[84 FR 23880, May 23, 2019]

§ 422.137 Medicare Advantage Utilization Management Committee.

(a) *General.* An MA organization that uses utilization management (UM) policies and procedures, including prior authorization (PA), must establish a UM committee that is led by a plan's medical director (described in § 422.562(a)(4)).

(b) *Limit on use of UM policies and procedures.* An MA plan may not use any UM policies and procedures for basic or supplemental benefits on or after January 1, 2024 unless those policies and procedures have been reviewed and approved by the UM committee.

(c) *Utilization Management Committee Composition.* The UM committee must—

(1) Include a majority of members who are practicing physicians.

(2) Include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan.

(3) Include at least one practicing physician who is an expert regarding care of elderly or disabled individuals.

(4) Include members representing various clinical specialties (for example, primary care, behavioral health) to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies.

(d) *Utilization Management Committee Responsibilities.* The UM committee must—

(1) At least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. Such review must consider:

(i) The services to which the utilization management applies;

(ii) Coverage decisions and guidelines for Traditional Medicare, including NCDs, LCDs, and laws; and

(iii) Relevant current clinical guidelines.

(2) Approve only utilization management policies and procedures that:

(i) Use or impose coverage criteria that comply with the requirements and standards at § 422.101(b);

(ii) For prior authorization policies, comply with requirements and standards at § 422.138;

(iii) Comply with the standards in § 422.202(b)(1); and

(iv) Apply and rely on medical necessity criteria that comply with § 422.101(c)(1).

(3) Revise the utilization management policies and procedures as necessary to comply with the standards in this regulation, including removing requirements for UM for services and items that no longer warrant UM.

(4) Clearly articulate and document processes to determine that the requirements under paragraphs (c)(1) through (4) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(5) Document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request.

[88 FR 22331, Apr. 12, 2023]

§ 422.138 Prior authorization.

(a) *Requirement.* When a coordinated care plan, as specified in § 422.4(a)(iii) (including MSA network plans), uses prior authorization processes in connection with basic benefits or supplemental benefits, the MA organization must comply with the requirements in this section. (MA PFFS are not permitted to use prior authorization policies or ''prior notification'' policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the PFFS plan in advance that services will be furnished). Prior authorization processes include all policies and procedures used in prior authorization unless otherwise noted.

(b) *Application.* Prior authorization processes for coordinated care plans may only be used for one or more the following purposes:

(1) To confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service; or

(2) For basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1), or

(3) For supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate.

(c) *Effect of prior authorization or pre-service approval.* If the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986 of this chapter) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. The definitions of the terms ''reliable evidence'' and ''similar fault'' in § 405.902 of this chapter apply to this provision.

[88 FR 22331, Apr. 12, 2023]

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 that offers one or more MA plan must have, for each plan, an ongoing quality improvement program that meets applicable requirements of this section for the service it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must do all of the following:

(1) Create a quality improvement program plan that sufficiently outlines the elements of the plan's quality improvement program.

(2) Have a chronic care improvement program that meets the requirements

of paragraph (c) of this section concerning elements of a chronic care program and addresses populations identified by CMS based on a review of current quality performance.

(3) [Reserved]

(4) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

(5) Incorporate one or more activities that reduce disparities in health and health care. These activities must be broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparities in health and health care.

(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) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those under paragraph (b)(3)(i) of this section.

(iii) 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.

(5) All coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

(6) For 2021 Star Ratings only, MA organizations are not required to submit HEDIS and CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings.

(c) *Chronic care improvement program requirements.* (1) Develop criteria for a chronic care improvement program. These criteria must include the following:

(i) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program.

(ii) Mechanisms for monitoring MA enrollees that are participating in the chronic improvement program and evaluating participant outcomes such as changes in health status.

(iii) Performance assessments that use quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or research.

(iv) Systematic and ongoing follow-up on the effect of the program.

(2) The organization must report the status and results of each program to CMS as requested.

(d) [Reserved]

(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) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those described under paragraph (e)(2)(i) of this section.

(iii) Evaluate the continuity and coordination of care furnished to enrollees.

(iv) 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.

(g) *Special requirements for specialized MA plans for special needs individuals*. All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. SNPs must submit their model of care (MOC), as defined under §422.101(f), to CMS for NCQA evaluation and approval, in accordance with CMS guidance. In addition to the requirements under paragraphs (a) and (f) of this section, a SNP must conduct a quality improvement program that does the following:

(1) Provides for the collection, analysis, and reporting of data that measures health outcomes and indices of quality pertaining to its targeted special needs population (that is, dual-eligible, institutionalized, or chronic condition) at the plan level.

(2) Measures the effectiveness of its model of care through the collection, aggregation, analysis, and reporting of data that demonstrate the following:

(i) Access to care as evidenced by measures from the care coordination domain (for example, service and benefit utilization rates, or timeliness of referrals or treatment).

(ii) Improvement in beneficiary health status as evidenced by measures from functional, psychosocial, or clinical domains (for example, quality of life indicators, depression scales, or chronic disease outcomes).

(iii) Staff implementation of the SNP model of care as evidenced by measures of care structure and process from the continuity of care domain (for example, National Committee for Quality Assurance accreditation measures or medication reconciliation associated with care setting transitions indicators).

(iv) Comprehensive health risk assessment as evidenced by measures from the care coordination domain (for example, accuracy of acuity stratification, safety indicators, or timeliness of

initial assessments or annual reassessments).

(v) Implementation of an individualized plan of care as evidenced by measures from functional, psychosocial, or clinical domains (for example, rate of participation by IDT members and beneficiaries in care planning).

(vi) A provider network having targeted clinical expertise as evidenced by measures from medication management, disease management, or behavioral health domains.

(vii) Delivery of services across the continuum of care.

(viii) Delivery of extra services and benefits that meet the specialized needs of the most vulnerable beneficiaries as evidenced by measures from the psychosocial, functional, and end-of-life domains.

(ix) Use of evidence-based practices and nationally recognized clinical protocols.

(x) Use of integrated systems of communication as evidenced by measures from the care coordination domain (for example, call center utilization rates, rates of beneficiary involvement in care plan development, etc.).

(3) Makes available to CMS information on quality and outcomes measures that will—

(i) Enable beneficiaries to compare health coverage options; and

(ii) Enable CMS to monitor the plan's model of care performance.

(h) *Requirements for MA private-fee-for-service plans and Medicare medical savings account plans.* MA PFFS and MSA plans are subject to the requirement that may not exceed the requirement specified in § 422.152(e).

[70 FR 4723, Jan. 28, 2005, as amended at 70 FR 52026, Sept. 1, 2005; 73 FR 54249, Sept. 18, 2008; 75 FR 19805, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011; 80 FR 7959, Feb. 12, 2015; 83 FR 16725, Apr. 16, 2018; 85 FR 19290, Apr. 6, 2020; 88 FR 22332, Apr. 12, 2023]

§ 422.153 Use of quality improvement organization review information.

CMS will acquire from quality improvement organizations (QIOs) as defined in part 475 of this chapter data collected under section 1886(b)(3)(B)(viii) of the Act and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and may use it for the following functions:

(a) Enable beneficiaries to compare health coverage options and select among them.

(b) Evaluate plan performance.

(c) Ensure compliance with plan requirements under this part.

(d) Develop payment models.

(e) Other purposes related to MA plans as specified by CMS.

[76 FR 26546, May 6, 2011]

§ 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.* The deeming process should focus on evaluating and assessing the overall quality improvement (QI) program. However, the chronic care improvement programs (CCIPs) will be excluded from the deeming process.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

(7) The requirements listed in § 423.165 (b)(1) through (3) of this chapter for MA organizations that offer prescription drug benefit 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) *Authority.* Nothing in this subpart limits CMS' authority under subparts K and O of this part, including but not limited to, the ability to impose intermediate sanctions, civil money penalties, and terminate a contract with an MA organization.

[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; 75 FR 19806, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011; 84 FR 15829, Apr. 16, 2019]

§ 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]

§ 422.160 Basis and scope of the Medicare Advantage Quality Rating System.

(a) *Basis.* This subpart is based on sections 1851(d), 1852(e), 1853(o) and 1854(b)(3)(iii), (v), and (vi) of the Act and the general authority under section 1856(b) of the Act requiring the establishment of standards consistent with and to carry out Part C.

(b) *Purpose.* Ratings calculated and assigned under this subpart will be used by CMS for the following purposes:

(1) To provide comparative information on plan quality and performance to beneficiaries for their use in making knowledgeable enrollment and coverage decisions in the Medicare program.

(2) To provide quality ratings on a 5-star rating system to be used in determining quality bonus payment (QBP) status and in determining rebate retention allowances.

(3) To provide a means to evaluate and oversee overall and specific compliance with certain regulatory and contract requirements by MA plans, where appropriate and possible to use data of the type described in § 422.162(c).

(c) *Applicability.* Except for § 422.162(b)(3), the regulations in this subpart will be applicable beginning with the 2019 measurement period and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract year and used to assign QBP ratings for the 2022 payment year.

[83 FR 16725, Apr. 16, 2018]

§ 422.162 Medicare Advantage Quality Rating System.

(a) *Definitions.* In this subpart the following terms have the meanings:

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.

Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.

Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy, or have disability status in that contract (or plan as applicable).

Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify the four cut points resulting in the creation of five levels (one for each Star Rating), such that the scores in the same Star Rating level are as similar as possible and the scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.

Consolidation means when an MA organization that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.

Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut

point. A cut point cap can restrict upward movement, downward movement, or both.

Display page means the CMS website on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.

Domain rating means the rating that groups measures together by dimensions of care.

Dual-eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

Health equity index means an index that summarizes contract performance among those with specified social risk factors (SRFs) across multiple measures into a single score.

HEDIS is the Healthcare Effectiveness Data and Information Set which is a widely used set of performance measures in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA). HEDIS data include clinical measures assessing the effectiveness of care, access/availability measures, and service use measures.

Highest rating means the overall rating for MA–PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.

Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments in § 422.166(f).

HOS means the Medicare Health Outcomes Survey which is the first patient reported outcomes measure that was used in Medicare managed care. The goal of the Medicare HOS program is to gather valid, reliable, and clinically meaningful health status data in the Medicare Advantage (MA) program for use in quality improvement activities, pay for performance, program oversight, public reporting, and improving health. All managed care organizations with MA contracts must participate.

Low income subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see § 423.34 of this chapter for definition of a low-income subsidy eligible individual).

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. By leaving out one of the 10 groups for each run, 9 of the 10 groups, which is 90 percent of the applicable measure scores, are used for each run of the clustering algorithm. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

Measurement period means the period for which data are collected for a measure or the performance period that a measures covers.

Measure score means the numeric value of the measure or an assigned 'missing data' message.

Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1–5 star scale.

Overall rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.

Part C summary rating means a global rating that summarizes the health plan quality and performance on Part C measures.

Part D summary rating means a global rating that summarizes prescription drug plan quality and performance on Part D measures.

Plan benefit package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by Part D plan sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.

Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (''signal'') rather than random variation

(''noise''); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile −3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

Reward factor means a rating-specific factor added to the contract's summary or overall ratings (or both) if a contract has both high and stable relative performance.

Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same.

Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.

Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3, or 4, then the value should be rounded down by deleting the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place deleted.

Tukey outer fence outliers are measure scores that are below a certain point (first quartile − 3.0 × (third quartile − first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)).

(b) *Contract ratings*—(1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA–PD contract, and a Part C summary rating for each MA-only contract using the 5-star rating system described in this subpart. Measures are assigned stars at the contract level and weighted in accordance with §422.166(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with §422.166(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with §422.166(c), with the applicable adjustments provided in paragraph (f) of this section. Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with §422.166(d), with the applicable adjustments provided in paragraph (f) of this section. CMS includes the Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

(2) *Plan benefit packages.* All plan benefit packages (PBPs) offered under an MA contract have the same overall and/or summary Star Ratings as the contract under which the PBP is offered by the MA organization. Data from all the PBPs offered under a contract are used to calculate the measure and domain ratings for the contract except for Special Needs Plan (SNP)-specific measures collected at the PBP level; a contract level score for such measures is calculated using an enrollment-weighted mean of the PBP scores and enrollment reported as part of the measure specification in each PBP.

(3) *Contract consolidations.* (i) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS assigns Star Ratings for the first and second years following the consolidation based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) as provided in paragraph (b)(3)(iv) of this section. Paragraph (b)(3)(iii) of this section is applied to subsequent years that are not addressed in paragraph (b)(3)(ii) of this section for assigning the QBP rating.

(ii) For the first year after a consolidation, CMS will determine the QBP

status of a contract using the enrollment-weighted means (using traditional rounding rules) of what would have been the QBP Ratings of the surviving and consumed contracts based on the contract enrollment in November of the year the preliminary QBP ratings were released in the Health Plan Management System (HPMS).

(iii) In subsequent years following the first year after the consolidation, CMS will determine QBP status based on the consolidated entity's Star Ratings displayed on Medicare Plan Finder.

(iv) The Star Ratings posted on Medicare Plan Finder for contracts that consolidate are as follows:

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures, call center measures, and improvement measures. The survey-based measures will use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures will use average enrollment during the study period. The Part C and D improvement measures are not calculated for first year consolidations.

(*2*) For contract consolidations approved on or after January 1, 2022, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except for HEDIS, CAHPS, and HOS. HEDIS and HOS measure data are scored as reported. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except HEDIS, CAHPS, and HOS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(v) This provision governing the Star Ratings of surviving contracts is applicable to contract consolidations that are approved on or after January 1, 2019.

(4) *Quality bonus payment ratings.* (i) For contracts that receive a numeric Star Rating, the final quality bonus payment (QBP) rating for the contract is released in April of each year for the following contract year. The QBP rating is the contract's highest rating from the Star Ratings published by CMS in October of the calendar year that is 2 years before the contract year to which the QBP rating applies.

(ii) The contract QBP rating is applied to each plan benefit package offered under the contract.

(c) *Data sources.* (1) CMS bases Part C Star Ratings on the type of data specified in section 1852(e) of the Act and on CMS administrative data. Part C Star Ratings measures reflect structure, process, and outcome indices of quality. This includes information of the following types: Clinical data, beneficiary experiences, changes in physical and mental health, benefit administration information and CMS administrative data. Data underlying Star Ratings measures may include survey data, data separately collected and used in oversight of MA plans' compliance with MA requirements, data submitted by plans, and CMS administrative data.

(2) MA organizations are required to collect, analyze, and report data that permit measurement of health outcomes and other indices of quality. MA organizations must provide unbiased, accurate, and complete quality data described in paragraph (c)(1) of this section to CMS on a timely basis as requested by CMS.

[83 FR 16725, Apr. 16, 2018, as amended at 84 FR 15829, Apr. 16, 2019; 85 FR 33907, June 2, 2020; 86 FR 6097, Jan. 19, 2021; 88 FR 22332, Apr. 12, 2023]

§ 422.164 Adding, updating, and removing measures.

(a) *General.* CMS adds, updates, and removes measures used to calculate the Star Ratings as provided in this section. CMS lists the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings.

(b) *Review of data quality.* CMS reviews the quality of the data on which performance, scoring and rating of a measure is based before using the data to score and rate performance or in calculating a Star Rating. This includes review of variation in scores among MA organizations and Part D plan sponsors, and the accuracy, reliability, and validity of measures and performance data before making a final determination about inclusion of measures in each year's Star Ratings.

(c) *Adding measures.* (1) CMS will continue to review measures that are nationally endorsed and in alignment with the private sector, such as measures developed by National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA), or endorsed by the National Quality Forum for adoption and use in the Part C and Part D Quality Ratings System. CMS may develop its own measures as well when appropriate to measure and reflect performance specific to the Medicare program.

(2) In advance of the measurement period, CMS will announce potential new measures and solicit feedback through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then subsequently will propose and finalize new measures through rulemaking.

(3) New measures added to the Part C Star Ratings program will be on the display page on *www.cms.gov* for a minimum of 2 years prior to becoming a Star Ratings measure.

(4) A measure will remain on the display page for longer than 2 years if CMS finds reliability or validity issues with the measure specification.

(d) *Updating measures*—(1) *Non-substantive updates.* For measures that are already used for Star Ratings, CMS will update measures so long as the changes in a measure are not substantive. CMS will announce non-substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Non-substantive measure specification updates include those that—

(i) Narrow the denominator or population covered by the measure;

(ii) Do not meaningfully impact the numerator or denominator of the measure;

(iii) Update the clinical codes with no change in the target population or the intent of the measure;

(iv) Provide additional clarifications:

(A) Adding additional tests that would meet the numerator requirements;

(B) Clarifying documentation requirements;

(C) Adding additional instructions to identify services or procedures; or

(v) Add alternative data sources.

(2) *Substantive updates.* For measures that are already used for Star Ratings, in the case of measure specification updates that are substantive updates not subject to paragraph (d)(1) of this section, CMS will propose and finalize these measures through rulemaking similar to the process for adding new measures. CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Once the update has been made to the measure specification by the measure steward, CMS may continue collection of performance data for the legacy measure and include it in Star Ratings until the updated measure has been on display for 2 years. CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings as specified in paragraph (c) of this section.

(e) *Removing measures.* (1) CMS will remove a measure from the Star Ratings program as follows:

(i) When the clinical guidelines associated with the specifications of the

measure change such that the specifications are no longer believed to align with positive health outcomes; or

(ii) A measure shows low statistical reliability.

(iii) The measure steward other than CMS retires a measure.

(2) CMS will announce in advance of the measurement period the removal of a measure based upon its application of this paragraph (e) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period.

(f) *Improvement measure.* CMS will calculate improvement measure scores based on a comparison of the measure scores for the current year to the immediately preceding year as provided in this paragraph (f); the improvement measure score would be calculated for Parts C and D separately by taking a weighted sum of net improvement divided by the weighted sum of the number of eligible measures.

(1) *Identifying eligible measures.* Annually, the subset of measures to be included in the Part C and Part D improvement measures will be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. CMS identifies measures to be used in the improvement measures if the measures meet all of the following:

(i) CMS will include only measures available for the current and previous year in the improvement measures and that have numeric value scores in both the current and prior year.

(ii) CMS will exclude any measure for which there was a substantive specification change from the previous year.

(iii) CMS will exclude any measures that are already focused on improvement in MA organization performance from year to year.

(iv) The Part C improvement measure will include only Part C measure scores; the Part D improvement measure will include only Part D measure scores.

(v) CMS excludes any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

(2) *Determining eligible contracts.* CMS will calculate an improvement score only for contracts that have numeric measure scores for both years in at least half of the measures identified for use applying the standards in paragraphs (f)(1)(i) through (iv) of this section.

(3) *Special rules for calculation of the improvement score.* For any measure used for the improvement measure for which a contract received 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change and included in the count of measures used to determine eligibility for the measure (that is, for the denominator of the improvement measure score).

(4) *Calculation of the improvement score.* The improvement measure will be calculated as follows:

(i) The improvement change score (the difference in the measure scores in the 2-year period) will be determined for each measure that has been designated an improvement measure and for which a contract has a numeric score for each of the 2 years examined.

(ii) Each contract's improvement change score per measure will be categorized as a significant change or not a significant change by employing a two-tailed t-test with a level of significance of 0.05.

(iii) The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.

(iv) The improvement measure score will then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.

(v) The improvement measure scores will be converted to measure-level Star Ratings by determining the cut points

using hierarchical clustering algorithms in accordance with § 422.166(a)(2)(i) through (iii).

(vi) The Part D improvement measure cut points for MA–PDs and PDPs will be determined using separate clustering algorithms in accordance with §§ 422.166(a)(2)(iii) and 423.186(a)(2)(iii) of this chapter.

(g) *Data integrity.* (1) CMS will reduce a contract's measure rating when CMS determines that a contract's measure data are inaccurate, incomplete, or biased; such determinations may be based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that have an impact on the accuracy, impartiality, or completeness of the data used for one or more specific measure(s).

(i) CMS will reduce HEDIS measures to 1 star when audited data are submitted to NCQA with a designation of ''biased rate'' or BR based on an auditor's review of the data or a designation of ''nonreport'' or NR.

(ii) CMS will reduce measures based on data that an MA organization must submit to CMS under § 422.516 to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with CMS data validation standards/substandards for data directly used to calculate the associated measure.

(iii) For the appeals measures, CMS will use statistical criteria to estimate the percentage of missing data for each contract (using data from multiple sources such as a timeliness monitoring study or audit information) to scale the star reductions to determine whether the data at the independent review entity (IRE) are complete. CMS will use scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.

(A)(*1*) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period is used to determine the scaled reduction.

(*2*) For contract consolidations approved on or after January 1, 2022, if there is a contract consolidation as described at § 422.162(b)(3), the TMP or audit data are combined for the consumed and surviving contracts before the methodology provided in paragraphs (g)(1)(iii)(B) through (O) of this section is applied.

(B) The determination of the Part C appeals measure IRE data reduction is done independently of the Part D appeals measure IRE data reduction.

(C) The reductions range from a one-star reduction to a four-star reduction; the most severe reduction for the degree of missing IRE data is a four-star reduction.

(D) The thresholds used for determining the reduction and the associated appeals measure reduction are as follows:

(*1*) 20 percent, 1 star reduction.

(*2*) 40 percent, 2 star reduction.

(*3*) 60 percent, 3 star reduction.

(*4*) 80 percent, 4 star reduction.

(E) If a contract receives a reduction due to missing Part C IRE data, the reduction is applied to both of the contract's Part C appeals measures.

(F) If a contract receives a reduction due to missing Part D IRE data, the reduction is applied to both of the contract's Part D appeals measures.

(G) The scaled reduction is applied after the calculation for the appeals measure-level Star Ratings. If the application of the scaled reduction results in a measure-level star rating less than 1 star, the contract will be assigned 1 star for the appeals measure.

(H) The Part C Calculated Error is determined using the quotient of number of cases not forwarded to the IRE and the total number of cases that should have been forwarded to the IRE. (The number of cases that should have been forwarded to the IRE is the sum of the number of cases in the IRE during the data collection or data sample period and the number of cases not forwarded to the IRE during the same period.)

(I) The Part D Calculated Error is determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases.

(J) The projected number of cases not forwarded to the IRE in a 3-month period is calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or

audit data by a constant determined by the data collection or data sample time period. The value of the constant will be 1.0 for contracts that submitted 3 months of data; 1.5 for contracts that submitted 2 months of data; and 3.0 for contracts that submitted 1 month of data.

(K) Contracts are subject to a possible reduction due to lack of IRE data completeness if both of the following conditions are met:

(*1*) The calculated error rate is 20 percent or more.

(*2*) The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

(L) A confidence interval estimate for the true error rate for the contract is calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent and an associated z of 1.959964 for a contract that is subject to a possible reduction.

(M) A contract's lower bound is compared to the thresholds of the scaled reductions to determine the IRE data completeness reduction.

(N) The reduction is identified by the highest threshold that a contract's lower bound exceeds.

(O) CMS reduces the measure rating to 1 star for the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project data for CMS's review to ensure the completeness of the contract's IRE data.

(2) CMS will reduce a measure rating to 1 star for additional concerns that data inaccuracy, incompleteness, or bias have an impact on measure scores and are not specified in paragraphs (g)(1)(i) through (iii) of this section, including a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements.

(h) *Review of sponsors' data.* (1) An MA organization may request that CMS or the IRE review its' contract's appeals data provided that the request is received by the annual deadline set by CMS.

(2) An MA organization may request that CMS review its' contract's Complaints Tracking Module (CTM) data provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

(i) [Reserved]

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§ 422.166 Calculation of Star Ratings.

(a) *Measure Star Ratings*—(1) *Cut points.* CMS will determine cut points for the assignment of a Star Rating for each numeric measure score by applying either a clustering or a relative distribution and significance testing methodology. For the Part D measures, CMS will determine MA–PD and PDP cut points separately.

(2) *Clustering algorithm for all measures except CAHPS measures.*

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

(ii) In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters.

(iii) The clustering algorithm for the improvement measure scores is done in two steps to determine the cut points for the measure-level Star Ratings. Clustering is conducted separately for improvement measure scores greater than or equal to zero and those with

improvement measure scores less than zero.

(A) Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating.

(B) Improvement scores less than zero would be assigned either 1 or 2 stars for the improvement Star Rating.

(3) *Relative distribution and significance testing for CAHPS measures.* The method combines evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data; no measure Star Rating is produced if the reliability of a CAHPS measure is less than 0.60. Low reliability scores are defined as those with at least 11 respondents, reliability greater than or equal to 0.60 but less than 0.75, and also in the lowest 12 percent of contracts ordered by reliability. The following rules apply:

(i) A contract is assigned 1 star if both of the criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met plus at least one of the criteria in paragraphs (a)(3)(i)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is lower than the 15th percentile; and

(B) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score;

(C) The reliability is not low; or

(D) Its average CAHPS measure score is more than one standard error below the 15th percentile.

(ii) A contract is assigned 2 stars if it does not meet the 1-star criteria and meets at least one of these three criteria:

(A) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability; or

(B) Its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability; or

(C) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.

(iii) A contract is assigned 3 stars if it meets at least one of these three criteria:

(A) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, and it is not statistically significantly different from the national average CAHPS measure score; or

(B) Its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile, the reliability is low, and the score is not statistically significantly lower than the national average CAHPS measure score; or

(C) Its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile, the reliability is low, and the score is not statistically significantly higher than the national average CAHPS measure score.

(iv) A contract is assigned 4 stars if it does not meet the 5-star criteria and meets at least one of these three criteria:

(A) Its average CAHPS measure score is at or above the 60th percentile and the measure does not have low reliability; or

(B) Its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability; or

(C) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.

(v) A contract is assigned 5 stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met plus at least one of the criteria in paragraphs (a)(3)(v)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is at or above the 80th percentile; and

(B) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score;

(C) The reliability is not low; or

(D) Its average CAHPS measure score is more than one standard error above the 80th percentile.

(4) *5-Star Scale.* Measure scores are converted to a 5-star scale ranging from 1 (worst rating) to 5 (best rating), with whole star increments for the cut points.

(b) *Domain Star Ratings.* (1)(i) CMS groups measures by domains solely for purposes of public reporting the data on Medicare Plan Finder. They are not

used in the calculation of the summary or overall ratings. Domains are used to group measures by dimensions of care that together represent a unique and important aspect of quality and performance.

(ii) The 5 domains for the MA Star Ratings are: Staying Healthy: Screenings, Tests and Vaccines; Managing Chronic (Long Term) Conditions; Member Experience with Health Plan; Member Complaints and Changes in the Health Plan's Performance; and Health Plan Customer Service. The 4 domains for the Part D Star Ratings are: Drug Plan Customer Service; Member Complaints and Changes in the Drug Plan's Performance; Member Experience with the Drug Plan; and Drug Safety and Accuracy of Drug Pricing.

(2) CMS calculates the domain ratings as the unweighted mean of the Star Ratings of the included measures.

(i) A contract must have scores for at least 50 percent of the measures required to be reported for that contract type for that domain to have a domain rating calculated.

(ii) The domain ratings are on a 1- to 5-star scale ranging from 1 (worst rating) to 5 (best rating) in whole star increments using traditional rounding rules.

(c) *Part C summary ratings.* (1) CMS will calculate the Part C summary ratings using the weighted mean of the measure-level Star Ratings for Part C, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

(2)(i) A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have the summary rating calculated.

(ii) The Part C improvement measure is not included in the count of the minimum number of rated measures.

(3) The summary ratings are on a 1- to 5-star scale ranging from 1 (worst rating) to 5 (best rating) in half-star increments using traditional rounding rules.

(d) *Overall MA–PD rating.* (1) The overall rating for a MA–PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with the applicable adjustments provided in paragraph (f) of this section.

(2)(i) An MA–PD must have both Part C and Part D summary ratings and scores for at least 50 percent of the measures required to be reported for the contract type to have the overall rating calculated.

(ii) The Part C and D improvement measures are not included in the count of measures needed for the overall rating.

(iii) Any measures that share the same data and are included in both the Part C and Part D summary ratings will be included only once in the calculation for the overall rating.

(iv) The overall rating is on a 1- to 5-star scale ranging from 1 (worst rating) to 5 (best rating) in half-increments using traditional rounding rules.

(v) Low enrollment contracts (as defined in § 422.252) and new MA plans (as defined in § 422.252) do not receive an overall and/or summary rating. They are treated as qualifying plans for the purposes of QBPs as described in § 422.258(d)(7) and as announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(vi) The QBP ratings for contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of low enrollment or new MA plans at § 422.252 are assigned as follows:

(A) For a new contract under an existing parent organization that has other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the QBP rating assigned is the enrollment-weighted average highest rating of the parent organization's other MA contract(s) that are active as of the April when the final QBP ratings are released under § 422.162(b)(4). The Star Ratings used in this calculation are the rounded stars (to the whole or half star) that are publicly displayed on *www.medicare.gov*. The enrollment figures used in the enrollment-weighted calculations are the

November enrollment in the year the Star Ratings are released.

(B) For a new contract under a parent organization that does not have other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the MA Star Ratings for the previous 3 years are used and the QBP rating is the enrollment-weighted average of the MA contract(s)'s highest ratings from the most recent year rated for that parent organization.

(*1*) The Star Ratings had to be publicly reported on *www.medicare.gov*.

(*2*) The Star Ratings used in this calculation are rounded to the whole or half star.

(C) The enrollment figures used in the enrollment-weighted calculations are the November enrollment in the year the Star Ratings are released.

(D) The QBP ratings are updated for any changes in a contract's parent organization that are reflected in CMS records prior to the release of the final QBP ratings in April of each year.

(E) Once the QBP ratings are finalized in April of each year for the following contract year, no additional parent organization changes are used for purposes of assigning QBP ratings.

(e) *Measure weights*—(1) *General rules.* Subject to paragraphs (e)(2) and (3) of this section, CMS will assign weights to measures based on their categorization as follows.

(i) Improvement measures receive the highest weight of 5.

(ii) Outcome and Intermediate outcome measures receive a weight of 3.

(iii) Through the 2025 Star Ratings, patient experience and complaint measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, patient experience and complaint measures receive a weight of 2.

(iv) Through the 2025 Star Ratings, access measures receive a weight of 4. Starting with the 2026 Star Ratings and subsequent Star Ratings years, access measures receive a weight of 2.

(v) Process measures receive a weight of 1.

(2) *Rules for new measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. In subsequent years, the measure will be assigned the weight associated with its category.

(3) *Special rule for Puerto Rico.* Contracts that have service areas that are wholly located in Puerto Rico will receive a weight of zero for the Part D adherence measures for the summary and overall rating calculations and will have a weight of 3 for the adherence measures for the improvement measure calculations.

(f) *Completing the Part C summary and overall rating calculations.* CMS will adjust the summary and overall rating calculations to take into account the reward factor (if applicable) and the categorical adjustment index (CAI) as provided in this paragraph (f).

(1) *Reward factor.* Through the 2026 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level.

(i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall for MA–PDs; Part C summary for MA–PDs and MA-only; and Part D summary for MA–PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its ranking relative to all rated contracts in the rating type (overall for MA–PDs; Part C summary for MA–PDs and MA-only; and Part D summary for MA–PDs and PDPs). The weighted mean and weighted variance are compared separately for MA–PD and standalone Part D contracts (PDPs). The measure weights are specified in paragraph (e) of this section. Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean are calculated both with and without the improvement measures. For an MA–PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D

summary) with the improvement measure. For the 2022 Star Ratings only, since all contracts may have the improvement measure(s) excluded in the determination of their highest rating and summary rating(s), each contract's weighted variance and weighted mean are calculated both with and without the improvement measures.

(ii) Relative performance of the weighted variance (or weighted variance ranking) will be categorized as being high (at or above 70th percentile), medium (between the 30th and 69th percentile) or low (below the 30th percentile). Relative performance of the weighted mean (or weighted mean ranking) will be categorized as being high (at or above the 85th percentile), relatively high (between the 65th and 84th percentiles), or other (below the 65th percentile).

(iii) The combination of the relative variance and relative mean is used to determine the value of the reward factor to be added to the contract's summary and overall ratings as follows:

(A) A contract with low variance and a high mean will have a reward factor equal to 0.4.

(B) A contract with medium variance and a high mean will have a reward factor equal to 0.3.

(C) A contract with low variance and a relatively high mean will have a reward factor equal to 0.2.

(D) A contract with medium variance and a relatively high mean will have a reward factor equal to 0.1.

(E) A contract with all other combinations of variance and relative mean will have a reward factor equal to 0.0.

(iv) The reward factor is determined and applied before application of the CAI adjustment under paragraph (f)(2) of this section; the reward factor is based on unadjusted scores.

(2) *Categorical Adjustment Index.* CMS applies the categorical adjustment index (CAI) as provided in this paragraph (f)(2) to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE) or have disability status. The factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part C, Part D for MA–PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment described in paragraph (f)(1) of this section (if applicable).

(A) The adjustment factor is monotonic (that is, as the proportion of LIS/DE and disabled increases in a contract, the adjustment factor increases in at least one of the dimensions) and varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and disabled beneficiaries.

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year. The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period. Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(C) MA–PD contracts may be adjusted up to three times with the CAI; one for the overall Star Rating and one for each of the summary ratings (Part C and Part D).

(D) An MA-only contract may be adjusted only once for the CAI for the Part C summary rating.

(E) The CAI values are rounded and displayed with 6 decimal places.

(ii) In determining the CAI values, a measure will be excluded from adjustment if the measure meets any of the following:

(A) The measure is already case-mix adjusted for socioeconomic status.

(B) The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue.

(C) The measure is scheduled to be retired or revised.

(D) The measure is applicable only to SNPs.

(iii) The Star Ratings measures that remain after the exclusion criteria, paragraph (f)(2)(ii) of this section, have been applied will be adjusted for the determination of the CAI. CMS will announce the measures identified for adjustment in the calculations of the CAI under this paragraph (f)(2) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) The adjusted measures scores for the selected measures are determined using the results from regression models of beneficiary-level measure scores that adjust for the average within-contract difference in measure scores for MA or PDP contracts.

(A) A logistic regression model with contract fixed effects and beneficiary level indicators of LIS/DE and disability status is used for the adjustment.

(B) The adjusted measure scores are converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.

(v) The rating-specific CAI values will be determined using the mean differences between the adjusted and unadjusted Star Ratings (overall, Part C summary, Part D summary for MA–PDs and Part D summary for PDPs) in each final adjustment category.

(A) For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled using the enrollment data that parallels the previous Star Ratings year's data would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled).

(B) The initial categories are created using all groups formed by the initial LIS/DE and disabled groups.

(C) The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled).

(D) The mean difference within each final adjustment category by rating-type (overall, Part C, Part D for MA–PD, and Part D for PDPs) would be the CAI values for the next Star Ratings year.

(vi) CMS develops the model for the modified contract-level LIS/DE percentage for Puerto Rico using the following sources of information:

(A) The most recent data available at the time of the development of the model of both 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL. The data to develop the model will be limited to the 10 states, drawn from the 50 states plus the District of Columbia with the highest proportion of people living below the FPL, as identified by the 1-year ACS estimates.

(B) The Medicare enrollment data from the same measurement period as the Star Ratings' year. The Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries with mailing addresses in the 10 highest poverty states.

(vii) A linear regression model is developed to estimate the percentage of LIS/DE for a contacts that solely serve the population of beneficiaries in Puerto Rico.

(A) The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent.

(B) All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.

(C) The model's coefficient and intercept are updated annually and published in the Technical Notes.

(3) *Health equity index.* Starting with the 2027 Star Ratings year and subsequent Star Ratings years, CMS applies

a health equity index rating-specific factor to both the summary and overall ratings of contracts that qualify based on an assessment of contract performance on quality measures among enrollees with certain social risk factors (SRFs).

(i) The health equity index (HEI) is calculated separately for the overall rating for MA–PDs and cost contracts including the applicable Part C and D measures; Part C summary rating for MA-only, MA–PD, and cost contracts including the applicable Part C measures; Part D summary rating for MA–PDs and cost contracts including the applicable Part D measures; and Part D summary rating for PDPs including the applicable Part D measures.

(A) The SRFs included in the HEI are receipt of the low income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE), or having a disability. Enrollees will be identified as LIS/DE or as having a disability as specified in paragraph (f)(2)(i)(B) of this section. If a person meets the LIS/DE criteria for only one of the two measurement years included in the HEI, the data for that person for just that year are used. Measures that are case-mix adjusted in the Star Ratings are adjusted using all standard case-mix adjustors for the measure except for those adjusters that are the SRFs of interest in the index, are strongly correlated with the SRFs of interest, or are conceptually similar to the SRFs of interest.

(B) The HEI is calculated by combining measure-level scores for the subset of enrollees with SRFs of interest included in the HEI across the two most recent measurement years using a modeling approach that includes year as an adjustor to account for potential differences in performance across years and to adjust the data to reflect performance in the second of the 2 years of data used. Measure-level scores are used for contracts that have data for only the most recent year of the 2 years, but measure-level scores are not used for contracts that have data for only the first of the 2 years.

(ii) In determining the HEI scores, a measure will be excluded from the calculation of the index if the measure meets any of the following:

(A) The focus of the measurement is not the enrollee but rather the plan or provider.

(B) The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI.

(C) The measure is applicable only to SNPs.

(D) At least 25 percent of contracts are unable to meet the criteria specified in paragraph (f)(3)(iv) of this section. For Part D measures, this criterion is assessed separately for MA–PDs and cost contracts, and for PDPs.

(iii) The Star Ratings measures that remain after the exclusion criteria in paragraph (f)(3)(ii) of this section have been applied will be included in the calculation of the HEI. CMS will announce the measures being evaluated for inclusion in the calculation of the HEI under this paragraph (f)(3) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(iv) For a measure to be included in the calculation of a contract's HEI score, the measure must meet both of the following criteria:

(A) The measure must have a reliability of at least 0.7 for the contract when calculated for the combined subset of enrollees with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(B) The measure-specific denominator criteria must be met for the contract using only the combined subset of enrollees in the contract with the SRF(s) specified in paragraph (f)(3)(i)(A) of this section across 2 years of data.

(v) To calculate the rating-specific HEI score, the distribution of contract performance on each eligible measure for the subset of enrollees that have one or more of the specified SRFs will be assessed and separated into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving −1 point. The rating-specific HEI will then be calculated as the weighted sum of points across all measures included in the index using the Star Ratings measure weight for each measure divided by

the weighted sum of the number of eligible measures for the given contract. The measure weight for each measure is the weight used for the measure in the current Star Ratings year as specified in paragraph (e) of this section.

(vi) To have the HEI calculated, contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

(vii) In order to qualify for the full HEI reward, contracts must have percentages of enrollees with the specified SRFs combined greater than or equal to the contract-level median in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. In order to qualify for one-half of the HEI reward, contracts must have percentages of enrollees with SRFs greater than or equal to one-half of the contract-level median up to, but not including, the contract-level median percentage of enrollees with SRFs in the most recent year of data used to calculate the HEI and a rating-specific minimum index score of greater than zero. One-half of the contract-level median and the contract-level median enrollment percentages are assessed separately for contracts that offer Part C and stand-alone Part D contracts.

(A) For contracts with service areas wholly located in Puerto Rico, the percentage of enrollees that are LIS/DE or disabled is calculated by adding the number of DE/disabled enrollees to the estimated LIS percentage calculated by taking the percentage LIS/DE as calculated at §§ 422.166(f)(2)(vi) and (vii) and 423.186(f)(2)(vi) and (vii) and subtracting the percentage of DE enrollees.

(B) Contracts with service areas wholly located in Puerto Rico are excluded from the calculation of one-half of the contract-level median and the contract-level median.

(viii) For contracts that have percentages of enrollees with SRFs greater than or equal to the contract-level median enrollment percentage, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.4 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.4 if the contract receives a score of 1 on the HEI. For contracts that have percentages of enrollees with SRFs greater than or equal to one-half the median percentage of enrollees with SRFs up to, but not including, the contract-level median percentage of enrollees with SRFs, the HEI reward added to the contract's summary and overall ratings will vary from 0 to 0.2 on a linear scale, with a contract receiving 0 if the contract receives a score of 0 or less on the HEI and 0.2 if the contract receives a score of 1 on the HEI. The HEI reward is rounded and displayed with 6 decimal places. Contracts that cannot have an HEI score calculated (that is, contracts that are not scored on at least half of the measures included in the index) will not receive an HEI reward.

(ix) The HEI reward is calculated separately for, and then added to, the overall rating, Part C rating for MA–PDs and MA-only contracts (and cost contracts), Part D rating for MA–PDs (and cost contracts), and Part D rating for PDPs after the addition of the CAI as specified in paragraph (f)(2) of this section and application of the improvement measures as specified in paragraph (g) of this section and before the final overall and Part C and D summary ratings are calculated by rounding to the nearest half star.

(g) *Applying the improvement measure scores.* (1) CMS runs the calculations twice for the highest level rating for each contract-type (overall rating for MA–PD contracts and Part C summary rating for MA-only contracts), with the reward factor adjustment if applicable and the CAI adjustment, once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:

(i) If the highest rating for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is

done. The higher rating is used for the rating.

(ii) If the highest rating is less than 4 stars without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

(2) The Part C summary rating for MA–PDs will include the Part C improvement measure and the Part D summary rating for MA–PDs will include the Part D improvement measure.

(3) For 2022 Star Ratings only, CMS runs the calculations twice for the highest rating for each contract-type (overall rating for MA–PD contracts and Part C summary rating for MA-only contracts) and Part C summary rating for MA–PDs with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's highest and summary rating(s), CMS applies the following rules:

(i) For MA–PDs and MA-only contracts, a comparison of the highest rating with and without the improvement measure is done. The higher rating is used for the highest rating.

(ii) For MA–PDs, a comparison of the Part C summary rating with and without the improvement measure is done. The higher rating is used for the summary rating.

(h) *Posting and display of ratings.* For all ratings at the measure, domain, summary and overall level, posting and display of the ratings is based on there being sufficient data to calculate and assign ratings. If a contract does not have sufficient data to calculate a rating, the posting and display would be the flag ''Not enough data available.'' If the measurement period is prior to one year past the contract's effective date, the posting and display would be the flag ''Plan too new to be measured''.

(1) *Medicare Plan Finder Performance icons.* Icons are displayed on Medicare Plan Finder to note performance as provided in this paragraph (h)(1):

(i) *High-performing icon.* The high performing icon is assigned to an MA-only contract for achieving a 5-star Part C summary rating and an MA–PD contract for a 5-star overall rating.

(ii) *Low-performing icon.* (A) A contract receives a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon is calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years. If the contract had any combination of Part C or Part D summary ratings of 2.5 or lower in all 3 years of data, it is marked with a low performing icon. A contract must have a rating in either Part C or Part D for all 3 years to be considered for this icon.

(B) CMS may disable the Medicare Plan Finder online enrollment function (in Medicare Plan Finder) for Medicare health and prescription drug plans with the low performing icon; beneficiaries will be directed to contact the plan directly to enroll in the low-performing plan.

(2) *Plan preview of the Star Ratings.* CMS will have plan preview periods before each Star Ratings release during which MA organizations can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder.

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS calculates the Star Ratings as specified in paragraphs (i)(2) through (10) of this section for each contract that is an affected contract during the performance period for the applicable measures. We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory

or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (10) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) An affected contract with an exemption described in paragraph (i)(2)(ii) of this section receives the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(3) *HOS adjustments.* (i) An affected contract must administer the HOS survey unless exempt under paragraph (i)(3)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the HOS survey if the contract completes the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section during the measurement period.

(B) Requests and receives a CMS approved exemption.

(iii) Affected contracts with an exemption described in paragraph (i)(3)(ii) of this section receive the prior year's HOS and Healthcare Effectiveness Data and Information Set (HEDIS)-HOS measure stars and corresponding measure scores.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure. The adjustment is for 3 years after the extreme and uncontrollable circumstance.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that

begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(4) *HEDIS adjustments.* (i) An affected contract must report HEDIS data unless exempted under paragraph (i)(4)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from reporting HEDIS data if the contract completes the following:

(A) Demonstrates an inability to obtain both administrative and medical record data that are required for reporting HEDIS measures due to a FEMA-designated disaster in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) Affected contracts with an exemption described in paragraph (i)(4)(ii) of this section receive the prior year's HEDIS measure stars and corresponding measure scores.

(iv) Contracts that do not have an exemption defined in paragraph (i)(4)(ii) of this section may contact National Committee for Quality Assurance (NCQA) to request modifications to the samples for measures that require medical record review.

(v) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HEDIS measure.

(vi) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(5) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS holds the affected contract harmless by using the higher of the contract's summary or overall rating or both with and without including all of the applicable new measures.

(6) *Other Star Ratings measure adjustments.* (i) For all other measures except those measures identified in this paragraph (i)(6)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance receive the higher of the previous or current year's measure Star Rating (and corresponding measure score).

(ii) CMS does not adjust the scores or Star Ratings for the following measures, unless the exemption in paragraph (i)(6)(iii) of this section applies.

(A) Part C Call Center—Foreign Language Interpreter and TTY Availability.

(B) Part D Call Center—Foreign Language Interpreter and TTY Availability.

(iii) CMS adjusts the measures listed in paragraph (i)(6)(ii) of this section using the adjustments listed in paragraph (i)(6)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(iv) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and

uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(7) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section is excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract. Contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating.

(8) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless any of the exemptions described in paragraphs (i)(2)(ii), (i)(3)(ii), and (i)(4)(ii) of this section apply.Missing data includes data where there is a data integrity issue as defined at § 422.164(g)(1).

(9) *Cut points for non-CAHPS measures.* (i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(9)(i) of this section are used to assess all affected contracts' measure Star Ratings.

(10) *Reward Factor.* (i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

(ii) All affected contracts are eligible for the Reward Factor based on the calculations described in paragraph (i)(10)(i) of this section.

(11) *Special rules for the 2022 Star Ratings only.* For the 2022 Star Ratings only, CMS will not apply the provisions in paragraph (i)(9) or (10) of this section and CMS will not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

(12) *Special rules for the 2023 Star Ratings only.* For the 2023 Star Ratings only, for measures derived from the Health Outcomes Survey only, CMS does not apply the provisions in paragraph (i)(9) or (10) of this section and CMS does not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

(j) *Special rules for 2021 and 2022 Star Ratings only.* (1) For the 2021 Star Ratings:

(i) The measures calculated based on HEDIS data are calculated based on data from the 2018 performance period.

(ii) The measures calculated based on CAHPS data are calculated based on survey data collected from March through May 2019.

(iii) The measure-level change score calculation described at § 422.164(f)(4)(i) is not applied for HEDIS and CAHPS measures and the measure-level change score used for the 2020 Star Ratings is applied in its place for all HEDIS and CAHPS-based measures.

(iv) The provisions of § 422.164(g)(1) and (2) are not applied for the failure to submit HEDIS and CAHPS-based measures.

(v) [Reserved]

(2) [Reserved]

[83 FR 16725, Apr. 16, 2018, as amended at 84 FR 15830, Apr. 16, 2019; 85 FR 19290, Apr. 6, 2020; 85 FR 33907, June 2, 2020; 85 FR 54872, Sept. 2, 2020; 86 FR 6098, Jan. 19, 2021; 87 FR 27895, May 9, 2022; 88 FR 22332, Apr. 12, 2023]

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 current evidence in widely used treatment guidelines or clinical literature;

(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; 88 FR 22334, Apr. 12, 2023]

§ 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.

(c) An MA organization must follow a documented process that ensures compliance with the preclusion list provisions in § 422.222.

[65 FR 40324, June 29, 2000, as amended at 66 FR 47413, Sept. 12, 2001; 70 FR 4724, Jan. 28, 2005; 81 FR 80556, Nov. 15, 2016; 83 FR 16731, Apr. 16, 2018]

§ 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 all applicable requirements under subpart V of this part.

(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; 83 FR 16731, Apr. 16, 2018]

§ 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.

Combined Stop-Loss Insurance Deductible Table (Table PIP–1) means the table described and developed using the methodology in paragraph (f)(2)(iv) of this section.

Global capitation means a specific type of ''capitation'' that includes both professional and institutional services. Services covered by global capitation may also include prescription drug benefits and supplemental benefits as well as basic benefits (as those terms are defined in § 422.100(c)). For purposes of Tables PIP–1 and PIP–2 global capitation includes all Parts A and B services except hospice.

Net benefit premium means the total amount of stop-loss claims (90 percent of claims above the deductible) for that panel size divided by the panel size. It is determined for each panel size and shown in Table PIP–1, described in paragraph (f)(2)(iv) of this section. It is then used in Table PIP–2, described in paragraph (f)(2)(vi) of this section, to identify all separate institutional and separate professional deductible combinations that meet the stop-loss requirements for multi-specialty physician groups participating in PIPs.

Non-Risk Patient Equivalents (NPE) means the estimate of annual claims for physician rendered services for non-risk patients served by the physician or physician group divided by what the PMPY capitation for physician rendered services would be if the beneficiary were part of the risk arrangement. Both Medicare and non-Medicare patients are included in this calculation.

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.

Separate Stop-Loss Insurance Deductible Table (Table PIP–2) means the table described and developed using the methodology in paragraph (f)(2)(vi) of this section.

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)(A) Stop-loss protection must cover at least 90 percent of costs of referral services above the deductible or an actuarial equivalent amount of the costs of referral services that exceed the per-patient deductible limit. The single combined deductible for the required stop-loss protection for the various panel sizes for contract years beginning on or after January 1, 2019 is determined using the Combined Stop-Loss Insurance Deductible Table (Table PIP–1). For panel sizes not shown on Table PIP–1 and for values not shown on Table PIP–2, linear interpolation (between the table values) may be used to identify the maximum deductible(s) for the required stop-loss coverage. Tables PIP–1 and PIP–2 apply to only multi-specialty physician groups in global capitation arrangements with per-patient stop-loss insurance. For all other physician incentive plan arrangements, the MA organization must assure that the physician or physician group entering into the physician incentive plan arrangement is covered by actuarially equivalent stop-loss protection that meets the requirements of this regulation.

(B) Using Table PIP–1, the deductible is identified for the panel size that is the number of risk patients plus non-risk patient equivalents. Non-risk patient equivalents may add a maximum of $100,000 to the deductible. The deductible for the stop-loss insurance required to be provided for the physician or physician group is then based on the lesser of:

(*1*) The deductible for the risk patient panel size plus $100,000; and

(*2*) The deductible for the panel size that is the total of the number of risk patients plus non-risk patient equivalents.

(iv) Table 1 is developed and updated by CMS using the methodology in this paragraph. CMS publishes Table PIP–1 in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act) in advance of the bid due date for the upcoming year if CMS determines that an update would be prudent for that year.

(A) The stop-loss tables are calculated using claims data for a statistically valid sample of beneficiaries enrolled in Fee-for-Service Medicare Parts A and B from the most available recent year. The sample includes only claims for beneficiaries eligible for both Part A and Part B for whom Medicare is the primary insurer and excludes hospice claims. The estimate of medical group income is derived from payments for all Part A and Part B services (excluding hospice) in the sampled claims data (to emulate a multi-specialty practice). The central limit theorem is used to obtain the distribution of claim means for a multi-specialty group of any given panel size. The distribution of claim means is used to obtain, with 98 percent confidence, the point at which a multi-specialty group of a given panel size would, through referral services, lose no more than 25 percent of potential payments. This point is the deductible in Table PIP–1 for the given panel size.

(B) The 'net benefit premium' (NBP) column in Table PIP–1 is not used for computation of combined insurance but is used to determine the separate deductibles for professional services and institutional services in the *Separate Stop-Loss Insurance Deductible Table* (Table PIP–2).

(C) The NBP is computed by dividing the total amount of stop loss claims (90 percent of claims above the deductible) for that panel size by the panel size.

(v)(A) Insurance using separate deductibles for professional and institutional claims is permissible so long as the separate deductibles for institutional services and professional services are determined using Table 2 as described in paragraph (f)(2)(vi)(B) of this section. Table PIP–2 is developed and updated by CMS using the methodology in paragraph (f)(2)(vi). CMS publishes Table PIP–2 in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act) in advance of the bid due date for the upcoming year if CMS determines that an update would be prudent for that year.

(B) The maximum deductibles for each category of services (institutional and professional claims) are identified by using the net benefit premium (NBP) determined in Table PIP–1 as the starting point in Table PIP–2. Any combination of institutional and professional attachment points for which the NBP in Table PIP–2 is greater than the NBP determined in Table PIP–1 is permissible. Interpolation may be used to find the NBP values in Table PIP–2 that are closest to the NBP identified in Table PIP–1.

(vi) Table PIP–2 is developed using a methodology similar to that for Table PIP–1.

(A) Claims data are obtained as described in paragraph (f)(2)(iv)(A).

(B) Professional and institutional claims are defined and categorized based on industry standards and based on payments for Part A and Part B services.

(C) The central limit theorem is used to obtain the distribution of claim means and deductibles are obtained at the 98 percent confidence level.

(3) *Special insurance.* If there is a different type of stop-loss policy obtained by the physician group, it must be actuarially equivalent to the coverage shown in Tables PIP–1 and PIP–2. Actuarially equivalent deductibles are acceptable if the insurance is actuarially certified by an attesting actuary who fulfills all of the following requirements:

(i) Develops the deductibles to be actuarially equivalent to those coverages in the Tables.

(ii) Makes the computations in accordance with generally accepted actuarial principles and practices.

(iii) Meets the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(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; 83 FR 16731, Apr. 16, 2018; 83 FR 27914, June 15, 2018]

§ 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.)

(c) *Deemed request for Medicare payment rate.* A noncontract section 1861(u) of the Act provider of services that furnishes services to MA enrollees and submits the same information that it would submit for payment under Original Medicare is deemed to be seeking to be paid the amount it would be paid under Original Medicare unless the provider expressly notifies the MA organization in writing that it is billing an amount less than such amount.

(d) *Regional PPO payments in non-network areas.* An MA Regional PPO must pay non-contract providers the Original Medicare payment rate in those portions of its service area where it is providing access to services by non-network means under § 422.111(b)(3)(ii) 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 47490, Aug. 12, 2005; 76 FR 21564, Apr. 15, 2011]

§ 422.216 Special rules for MA private fee-for-service plans.

(a) *Payment to providers*—(1) *Payment rate.* (i) The MA organization must establish payment rates for plan covered items and services that apply to deemed providers. The MA organization may vary payment rates for providers in accordance with § 422.4(a)(3).

(ii) 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) *Noncontract providers.* The organization pays for services of noncontract providers in accordance with § 422.100(b)(2).

(3) *Services 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 amounts for services furnished to a beneficiary enrolled in an MA private fee-for-service plan must receive, and accept as payment in full, at least the amount (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 private fee-for-service plan must provide to plan enrollees, an appropriate explanation of benefits consistent with the requirements of § 422.111(b)(12).

(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; 73 FR 54250, Sept. 18, 2008; 77 FR 22167, Apr. 12, 2012]

§ 422.220 Exclusion of payment for basic benefits furnished under a private contract.

(a) Unless otherwise authorized in paragraph (b) or (c) of this section, an MA organization may not pay, directly or indirectly, on any basis, for basic benefits furnished to a Medicare enrollee by a physician (as defined in paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare contractor 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.

(b) An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner described in paragraph (a) of this section who has not signed a private contract with the beneficiary.

(c) An MA organization may make payment to a physician or practitioner described in paragraph (a) of this section for services that are not basic benefits but are provided to a beneficiary as a supplemental benefit consistent with § 422.102.

[86 FR 6098, Jan. 19, 2021]

§ 422.222 Preclusion list for contracted and non-contracted individuals and entities.

(a)(1)(i) Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item, service, or drug that is furnished, ordered, or prescribed by an individual or entity that is included on the preclusion list, defined in § 422.2.

(ii) With respect to MA providers that have been added to an updated preclusion list but are not currently excluded by the OIG, the MA organization must do all of the following:

(A) No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received or been prescribed an MA service, item, or drug from or by the individual or entity added to the preclusion list in this update.

(B)(*1*) Subject to paragraph (a)(1)(ii)(B)(*2*) of this section, must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section.

(*2*) Paragraph (a)(1)(ii)(B)(*1*) of this section applies only upon receipt of a claim from a precluded provider in Medicare Part C when—

(*i*) The MA organization has enough information on file to either copy the provider on the notification previously sent to the beneficiary or send a new notice informing the provider that they may not see plan beneficiaries due to their preclusion status; and

(*ii*) The claim is received after the claim denial or reject date in the preclusion file.

(C) Must not deny payment for a service, item, or drug furnished, ordered, or prescribed by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.

(2)(i) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with part 498 of this chapter.

(ii) If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(A) The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

(B) The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation must be filed jointly by the individual or entity and, as applicable, considered jointly under part 498 of this chapter.

(3)(i) Except as provided in paragraph (a)(3)(ii) of this section, an individual or entity will only be included on the preclusion list after the expiration of either of the following:

(A) If the individual or entity does not file a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list upon the expiration of the 60-day period in which the individual or entity may request a reconsideration; or

(B) If the individual or entity files a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list effective on the date on which CMS, if applicable, denies the individual's or entity's reconsideration.

(ii) An OIG excluded individual or entity is added to the preclusion list effective on the date of the exclusion.

(4) Payment denials based upon an individual's or entity's inclusion on the preclusion list are not appealable by beneficiaries.

(5)(i) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the individual's or entity's reenrollment bar.

(ii) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the individual or entity had they been enrolled and then revoked.

(iii) Except as provided in paragraph (a)(5)(iv) of this section, an individual or entity, regardless of whether they

are or were enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are as follows:—

(A) The severity of the offense.

(B) When the offense occurred.

(C) Any other information that CMS deems relevant to its determination.

(iv) In cases where an individual or entity is excluded by the OIG, the individual or entity must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(6) CMS has the discretion not to include a particular individual or entity on (or if warranted, remove the individual or entity from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to MA items, services, or drugs. In making a determination as to whether such circumstances exist, CMS takes into account:

(i) The degree to which beneficiary access to MA items, services, or drugs would be impaired; and

(ii) Any other evidence that CMS deems relevant to its determination.

(b) An MA organization that does not comply with paragraph (a) of this section may be subject to sanctions under § 422.750 and termination under § 422.510.

[83 FR 16733, Apr. 16, 2018, as amended at 84 FR 15831, Apr. 16, 2019]

§ 422.224 Payment to individuals and entities excluded by the OIG or included on the preclusion list.

(a) An MA organization may not pay, directly or indirectly, on any basis, for items or services furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2.

(b) If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in § 422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

[83 FR 16733, Apr. 16, 2018]

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 sections 1853 and 1858 of the Act, and is also based on section 1106 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, negotiation and approval of bids by CMS, and the release of MA bid submission data.

[81 FR 80556, Nov. 15, 2016]

§ 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.

Low enrollment contract means a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan.

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 (if any) an MA plan (except an MSA plan) charges

an enrollee for basic benefits as defined in § 422.100(c)(1), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of basic benefits as defined in § 422.100(c)(1) 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 basic benefits as defined in § 422.100(c)(1).

(2) The amount for coverage of basic prescription drug benefits under Part D (if any).

(3) The amount for provision of supplemental health care benefits (if any).

New MA plan means a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years. For purposes of 2022 quality bonus payments based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years.

Plan basic cost sharing means cost sharing that would be charged by a plan for basic benefits as defined in § 422.100(c)(1) 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 that reflects the nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c) of this part, (that is, a standardized benchmark). 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. The rules for determining county capitation rates are specific to a time period, as set forth at § 422.258(a). Effective 2012, the MA area-specific non-drug monthly benchmark amount is called the blended benchmark amount, and is determined according to the rules set forth under § 422.258(d) of this part.

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 basic benefits as defined in § 422.100(c)(1) 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; 76 FR 21564, Apr. 15, 2011; 84 FR 15832, Apr. 16, 2019; 85 FR 19290, Apr. 6, 2020; 86 FR 6098, Jan. 19, 2021; 87 FR 27895, May 9, 2022]

§ 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.

(4) CMS may decline to accept any or every otherwise qualified bid submitted by an MA organization or potential MA organization.

(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 basic benefits as defined in § 422.100(c)(1).

(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.

(i) MA plans offering additional telehealth benefits as defined in § 422.135(a) must exclude any capital and infrastructure costs and investments directly incurred or paid by the MA plan relating to such benefits from their bid submission for the unadjusted MA statutory non-drug monthly bid amount.

(ii) [Reserved]

(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 basic benefits as defined in § 422.100(c)(1) 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 fee-for-service 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).

(5) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles.

(i) A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review).

(ii) To be deemed a qualified actuary, the actuary must be a member of the American Academy of Actuaries.

(iii) Applicants may use qualified outside actuaries to prepare their bids.

(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 basic benefits as defined in § 422.100(c)(1);

(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 MA monthly MSA premium for basic benefits (as defined in § 422.252);

(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; 75 FR 19806, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011; 83 FR 16733, Apr. 16, 2018; 84 FR 15833, Apr. 16, 2019]

§ 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 and may decline to approve a bid if the plan sponsor proposes significant increases in cost sharing or decreases in benefits offered under the plan.

(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; 75 FR 19806, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011; 83 FR 16733, Apr. 16, 2018]

§ 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:

(i) For years before 2007, one-twelfth of the annual MA capitation rate (described at § 422.306) for the area, adjusted as appropriate for the purpose of risk adjustment.

(ii) For years 2007 through 2010, one-twelfth of the applicable amount determined under section 1853(k)(1) of the Act for the area for the year, adjusted as appropriate for the purpose of risk adjustment.

(iii) For 2011, one-twelfth of the applicable amount determined under 1853(k)(1) for the area for 2010.

(iv) Beginning with 2012, one-twelfth of the blended benchmark amount described in paragraph (d) of this section, subject to paragraph (d)(8) of this section and 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 amounts described in paragraph (a)(1) of this section for the year 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 amount determined under paragraph (a) of this section for the year 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.

(d) *Determination of the blended benchmark amount*—(1) *General rules.* For the purpose of paragraphs (a) and (b) of this section, the term blended benchmark amount for an area for a year means the sum of two components: the applicable amount determined under section 1853(k)(1) of the Act and the specified amount determined under section 1853(n)(2) of Act. The weights for each component are based on the phase-in period assigned each area, as described in paragraphs (d)(8) and (d)(9) of this section. At the conclusion of an area's phase-in period, the blended benchmark for an area for a year equals the section 1853(n)(2) of the Act specified amount described in paragraph (d)(2) of this section. The blended benchmark amount for an area for a year (which takes into account paragraph (d)(8) of this section), cannot exceed the applicable amount described in paragraph (d)(2) of this section that would be in effect but for the application of this paragraph.

(2) *Applicable amount.* For the purpose of paragraphs (a) and (b) of this section, the applicable amount determined under section 1853(k)(1) of the Act for a year is—

(i) In a rebasing year (described at § 422.306(b)(2), an amount equal to the greater of the average FFS expenditure amount at § 422.306(b)(2) for an area for a year and the minimum percentage increase rate at § 422.306(a) for an area for a year.

(ii) In a year when the amounts at § 422.306(b)(2) are not rebased, the minimum percentage increase rate at § 422.306(a) for the area for the year.

(iii) In no case the blended benchmark amount for an area for a year, determined taking into account paragraph (d)(8) of this section, be greater than the applicable amount at paragraph (d)(2) of this section for an area for a year.

(iv) Paragraph (d) of this section does not apply to the PACE program under section 1894 of Act.

(3) *Specified amount.* For the purpose of paragraphs (a) and (b) of this section, the specified amount under section 1853(n)(2) of the Act is the product of the base payment amount for an area for a year (adjusted as required under §422.306(c) and (d)) multiplied by the applicable percentage described in paragraph (d)(5) of this section for an area for a year.

(4) *Base payment amount.* The base payment amount is as follows:

(i) For 2012, the average FFS expenditure amount specified in §422.306(b)(2), determined for 2012.

(ii) For subsequent years, the average FFS expenditure amount specified in §422.306(b)(2).

(5) *Applicable percentage.* Subject to paragraph (d)(7) of this section, the applicable percentage is one of four values assigned to an area based on Secretary's determination of the quartile ranking of the area's average FFS expenditure amount (described at §422.306(b)(2) and adjusted as required at §422.306(c) and (d)), relative to this amount for all areas.

(i) For the 50 States or the District of Columbia, a county with an average FFS expenditure amount adjusted under §422.306(c) and (d) that falls in the—

(A) Highest quartile of such rates for all areas for the previous year receives an applicable percentage of 95 percent;

(B) Second highest quartile of such rates for all areas for the previous year receives an applicable percentage of 100 percent;

(C) Third highest quartile of such rates for all areas for the previous year receives an applicable percentage of 107.5 percent; or

(D) Lowest quartile of such rates for all areas for the previous year receives an applicable percentage of 115 percent.

(ii) To determine the applicable percentages for a territory, the Secretary ranks such areas for a year based on the level of the area's §422.306(b)(2) amount adjusted under §422.306(c) and (d), relative to the quartile rankings computed under paragraph (d)(5)(i) of this section.

(6) *Additional rules for determining the applicable percentage.* (i) In a contract year when the average FFS expenditure amounts from the previous year were rebased (according to the periodic rebasing requirement at §422.306(b)(2)), the Secretary must determine an area's applicable percentage based on a quartile ranking of the previous year's rebased FFS amounts adjusted under §422.306(c) and (d).

(ii) If, for a year after 2012, there is a change in the quartile in which an area is ranked compared to the previous year's ranking, the applicable percentage for the area in the year must be the average of the applicable percentage for the previous year and the applicable percentage that would otherwise apply for the area for the year in the absence of this transitional provision.

(7) *Increases to the applicable percentage for quality.* Beginning with 2012, the blended benchmark under paragraphs (a) and (b) of this section will reflect the level of quality rating at the plan or contract level, as determined by the Secretary. The quality rating for a plan is determined by the Secretary according to a 5-star rating system (based on the data collected under section 1852(e) of the Act) specified in subpart D of this part 422. Specifically, the applicable percentage under paragraph (d)(5) of this section must be increased according to criteria in paragraphs (d)(7)(i) through (v) of this section if the plan or contract is determined to be a qualifying plan or a qualifying plan in a qualifying county for the year.

(i) *Qualifying plan.* Beginning with 2012, a qualifying plan means a plan that had a quality rating of 4 stars or higher based on the most recent data available for such year. For a qualifying plan, the applicable percentage at paragraph (d)(5) of this section must be increased as follows:

(A) For 2012, by 1.5 percentage points.

(B) For 2013, by 3.0 percentage points.

(C) For 2014 and subsequent years, by 5.0 percentage points.

(ii) *Qualifying county.* (A) A *qualifying county* means a county that meets the following three criteria:

(*1*) Has an MA capitation rate that, in 2004, was based on the amount specified in section 1853(c)(1)(B) of the Act for a Metropolitan Statistical Area with a population of more than 250,000.

(*2*) Of the MA-eligible individuals residing in the county, at least 25 percent of such individuals were enrolled in MA plans as of December 2009.

(*3*) Has per capita fee-for-service spending that is lower than the national monthly per capita cost for expenditures for individuals enrolled under the Original Medicare fee-for-service program for the year.

(B) Beginning with 2012, for a qualifying plan serving a qualifying county, the increase to the applicable percentage described at paragraph (d)(7)(i) of this section must be doubled for the qualifying county.

(iii) MA organizations that fail to report data as required by the Secretary must be counted as having a rating of fewer than 3.5 stars at the plan or contract level, as determined by the Secretary.

(iv) *Application of applicable percentage increases to low enrollment contracts.* (A) For 2012, for an MA plan that the Secretary determines is unable to have a quality rating because of low enrollment, the Secretary treats this plan as a qualifying plan under paragraph (d)(7)(i) of this section.

(B) For 2013 and subsequent years, the Secretary develops a methodology to apply to MA plans with low enrollment (as defined by the Secretary) to determine whether a low enrollment contract is a qualifying plan.

(v) *Application of increases in applicable percentage to new MA plans.* A new MA plan (as defined at § 422.252) that meets criteria specified by the Secretary must be treated as a qualifying plan under paragraph (d)(7)(i) of this section, except that the applicable percentage must be increased as follows:

(A) For 2012, by 1.5 percentage points.

(B) For 2013, by 2.5 percentage points.

(C) For 2014 and subsequent years, by 3.5 percentage points.

(8) *Determination of phase-in period for the blended benchmark amount.* For 2012 through 2016, the blended benchmark amount for an area for a year depends on the phase-in period assigned to that area. The Secretary assigns one of three phase-in periods to each area: 2-year, 4 year, or 6 year. The phase-in period assigned to an area is based on the size of the difference between the 2010 applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount defined at paragraph (d)(8)(i) of this section.

(i) The projected 2010 benchmark amount is calculated once for the purpose of determining the phase-in period for an area. It is equal to one-half of the 2010 applicable amount at paragraph (d)(2) of this section and one-half of the specified amount at paragraph (d)(3) modified to apply to 2010 (as described in (d)(8)(ii) of this section).

(ii) To assign a phase-in period to an area, the specified amount is modified as if it applies to 2010, and is the product of—

(A) The 2010 base payment amount adjusted as required under § 422.306(c) of this part; and

(B) The applicable percentage determined as if the reference to the ''previous year'' at paragraph (d)(5) of this section were deemed a reference to 2010 and increased as follows:

(*1*) The increase at paragraph (d)(7)(i) of this section for a qualifying plan in the area is applied as if the reference to a qualifying plan for 2012 were deemed a reference for 2010; and

(*2*) The increase at paragraph (d)(7)(ii) of this section is applied as if the determination of a qualifying county were made for 2010.

(iii) *Two-year phase-in.* An area is assigned the 2-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is less than $30.

(iv) *Four-year phase-in.* An area is assigned the 4-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is at least $30 but less than $50.

(v) *Six-year phase-in.* An area is assigned the 6-year phase-in period if the difference between the applicable

amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is at least $50.

(9) *Impact of phase-in period on calculation of the blended benchmark amount*—(i) *Weighting for the 2-year phase-in.* (A) For 2012, the blended benchmark is the sum of one-half of the applicable amount at paragraph (d)(2) of this section and one-half of the specified amount at paragraph (d)(3) of this section.

(B) For 2013 and subsequent years, the blended benchmark equals the specified amount.

(ii) *Weighting for the 4-year phase-in.* The blended benchmark is the sum of the applicable amount at paragraph (d)(2) of this section and the specified amount at paragraph (d)(2) of this section in the following proportions:

(A) For 2012, three-fourths of the applicable amount for the area for the year and one-fourth of the specified amount for the area and year.

(B) For 2013, one-half of the applicable amount for the area for the year and one-half of the specified amount for the area and year.

(C) For 2014, one-fourth of the applicable amount for the area for the year and three-fourths of the specified amount for the area and year.

(D) For 2015 and subsequent years, the blended benchmark equals the specified amount for the area and year.

(iii) *Weighting for the 6-year phase-in.* The blended benchmark is the sum of the applicable amount at paragraph (d)(2) and the specified amount at paragraph (d)(3) of this section in the following proportions:

(A) For 2012, five-sixths of the applicable amount for the area and year and one-sixth of the specified amount for the area and year.

(B) For 2013, two-thirds of the applicable amount for the area and year and one-third of the specified amount for the area and year.

(C) For 2014, one-half of the applicable amount for the area and year and one-half of the specified amount for the area and for year.

(D) For 2015, one-third of the applicable amount for the area and year and two-thirds of the specified amount for the area and for year.

(E) For 2016, one-sixth of the applicable amount for the area and year and five-sixths of the specified amount for the area and for year.

(F) For 2017 and subsequent years, the blended benchmark equals the specified amount for the area and year.

[70 FR 4725, Jan. 28, 2005, as amended at 76 FR 21564, Apr. 15, 2011; 83 FR 16733, Apr. 16, 2018; 85 FR 33907, June 2, 2020]

§ 422.260 Appeals of quality bonus payment determinations.

(a) *Scope.* The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act. Such determinations are made based on the overall rating for MA–PDs and Part C summary rating for MA-only contracts for the contract assigned under subpart D of this part.

(b) *Definitions.* The following definitions apply to this section:

Quality bonus payment (QBP) means—

(i) Enhanced CMS payments to MA organizations based on the organization's demonstrated quality of its Medicare contract operations; or

(ii) Increased beneficiary rebate retention allowances based on the organization's demonstrated quality of its Medicare contract operations.

Quality bonus payment (QBP) determination methodology means the quality ratings system specified in subpart D of this part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP. (Low enrollment contracts and new MA plans are defined in § 422.252.)

Quality bonus payment (QBP) status means a MA organization's standing with respect to its qualification to—

(i) Receive a quality bonus payment, as determined by CMS; or

(ii) Retain a portion of its beneficiary rebates based on its quality rating, as determined by CMS.

(c) *Administrative review process for QBP status appeals.* (1) Reconsideration request. An MA organization may request reconsideration of its QBP status.

(i) The MA organization requesting reconsideration of its QBP status must do so by providing written notice to

CMS within 10 business days of the release of its QBP status. The request must specify the given measure(s) in question and the basis for reconsideration such as a calculation error or incorrect data was used to determine the QBP status. The error could impact an individual measure's value or the overall star rating.

(ii) The reconsideration official's decision is final and binding unless a request for an informal hearing is filed in accordance with paragraph (2) of this section.

(2) *Informal hearing request.* An MA organization may request an informal hearing on the record following the reconsideration official's decision regarding its QBP status.

(i) The MA organization seeking an appeal of the reconsideration official's decision regarding its QBP status must do so by providing written notice to CMS within 10 business days of the issuance of the reconsideration decision. The notice must specify the errors the MA organization asserts that CMS made in making the QBP determination and how correction of those errors could result in the organization's qualification for a QBP or a higher QBP.

(ii) The MA organization may not request an informal hearing of its QBP status unless it has already requested and received a reconsideration decision in accordance with paragraph (c)(1) of this section.

(iii) The informal hearing request must pertain only to the measure(s) and value(s) in question that precipitated the request for reconsideration.

(iv) The informal hearing is conducted by a CMS hearing officer on the record. The hearing officer receives no testimony, but may accept written statements with exhibits from each party in support of their position in the matter.

(v) The MA organization must provide clear and convincing evidence that CMS' calculations of the measure(s) and value(s) in question were incorrect.

(vi) The hearing officer issues the decision by electronic mail to the MA organization.

(vii) The hearing officer's decision is final and binding.

(3) *Limits to requesting an administrative review.* (i) CMS may limit the measures or bases for which a contract may request an administrative review of its QBP status.

(ii) An administrative review cannot be requested for the following: the methodology for calculating the star ratings (including the calculation of the overall star ratings); cut-off points for determining measure thresholds; the set of measures included in the star rating system; and the methodology for determining QBP determinations for low enrollment contracts and new MA plans.

(4) *Designation of a hearing officer.* CMS designates a hearing officer to conduct the appeal of the QBP status. The officer must be an individual who did not directly participate in the initial QBP determination.

(d) *Reopening of QBP determinations.* CMS may, on its own initiative, revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year. CMS may take this action on the basis of any credible information, including the information provided during the administrative review process that demonstrates that the initial QBP determination was incorrect.

[76 FR 21566, Apr. 15, 2011, as amended at 83 FR 16733, Apr. 16, 2018]

§ 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.

(g) *Prohibition on improper billing of premiums.* MA organizations shall not bill an enrollee for a premium payment period if the enrollee has had the premium for that period withheld from his or her Social Security, Railroad Retirement Board or Office of Personnel Management check.

(h) *Retroactive collection of premiums.* In circumstances where retroactive collection of premium amounts is necessary and the enrollee is without fault in creating the premium arrearage, the Medicare Advantage organization shall offer the enrollee the option of payment either by lump sum, by equal monthly installment spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Medicare Advantage organization. For monthly installments, for example, if 7 months of premiums are due, the member would have at least 7 months to repay.

[63 FR 18134, Apr. 14, 1998, as amended at 74 FR 1541, Jan. 12, 2009]

§ 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 MA statutory non-drug monthly bid amount (defined at § 422.254(b)(1)(i)), 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 basic benefits defined in § 422.100(c)(1) by a local MA plan, 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 amount for coverage of basic benefits defined in § 422.100(c)(1) by a regional MA plan, 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.

[70 FR 4725, Jan. 28, 2005, as amended at 84 FR 15833, Apr. 16, 2019]

§ 422.266 Beneficiary rebates.

(a) *Calculation of rebate.* (1) For 2006 through 2011, 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.

(2) For 2012 and subsequent years, an MA organization must provide to the enrollee a monthly rebate equal to a specified percentage of the average per capita savings (if any) at § 422.264(b) for MA local plans and § 422.264(d) for MA regional plans. For 2012 and 2013, this percentage is based on a combination of the (a)(1) rule of 75 percent and the (a)(2)(ii) rules that set the percentage based on the plan's quality rating under a 5 star rating system, as determined by the Secretary under § 422.258(d)(7). For 2014 and subsequent years, this percentage is determined based only on the paragraph (a)(2)(ii) of this section.

(i) *Applicable rebate percentage for 2012 and 2013.* Subject to paragraphs (a)(2)(iii) and (iv) of this section, the transitional applicable rebate percentage is, for a year, the sum of two amounts as follows:

(A) *For 2012.* Two-thirds of the old proportion of 75 percent of the average per capita savings; and one-third of the new proportion assigned the plan under paragraph (a)(2)(ii) of this section, based on the quality rating specified in § 422.258(d)(7).

(B) *For 2013.* One-third of the old proportion of 75 percent of the average per capita savings; and two-thirds of the new proportion assigned the plan under paragraph (d)(2)(ii) of this section, based on the quality rating at § 422.258(d)(7).

(ii) *Final applicable rebate percentage.* For 2014 and subsequent years, and subject to paragraphs (a)(2)(iii) and (iv) of this section, the final applicable rebate percentage is as follows:

(A) In the case of a plan with a quality rating under such system of at least 4.5 stars, 70 percent of the average per capita savings;

(B) In the case of a plan with a quality rating under such system of at least 3.5 stars and less than 4.5 stars, 65 percent of the average per capita savings.

(C) In the case of a plan with a quality rating under such system of less than 3.5 stars, 50 percent of the average per capita savings.

(iii) *Treatment of low enrollment contracts.* For 2012, in the case of a plan described at § 422.258(d)(7)(iv), the plan must be treated as having a rating of 4.5 stars for the purpose of determining the beneficiary rebate amount.

(iv) *Treatment of new MA plans.* For 2012 or a subsequent year, a new MA plan defined at § 422.252 that meets the criteria specified by the Secretary for purposes of § 422.258(d)(7)(v) must be treated as a qualifying plan under § 422.258(d)(7)(i), except that plan must be treated as having a rating of 3.5 stars for purposes of determining the beneficiary rebate amount.

(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.≤[70 FR 4725, Jan. 28, 2005, as amended at 76 FR 21567, Apr. 15, 2011]

§ 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.

§ 422.272 Release of MA bid pricing data.

(a) *Terminology.* For purposes of this section, the term ''MA bid pricing data'' means the following information that MA organizations must submit for each MA plan bid for the annual bid submission:

(1) The pricing-related information described at § 422.254(a)(1); and

(2) The information required for MSA plans, described at § 422.254(e).

(b) *Release of MA bid pricing data.* Subject to paragraph (c) of this section and to the annual timing identified in paragraph (d) of this section, CMS will release to the public MA bid pricing data for MA plan bids accepted or approved by CMS for a contract year under § 422.256. The annual release will contain MA bid pricing data from the

final list of MA plan bids accepted or approved by CMS for a contract year that is at least 5 years prior to the upcoming calendar year.

(c) *Exclusions from release of MA bid pricing data.* For the purpose of this section, the following information is excluded from the data released under paragraph (b) of this section:

(1) For an MA plan bid that includes Part D benefits, the information described at § 422.254(b)(1)(ii), (c)(3)(ii), and (c)(7).

(2) Additional information that CMS requires to verify the actuarial bases of the bids for MA plans for the annual bid submission, as follows:

(i) Narrative information on base period factors, manual rates, cost-sharing methodology, optional supplement benefits, and other required narratives.

(ii) Supporting documentation.

(3) Any information that could be used to identify Medicare beneficiaries or other individuals.

(4) Bid review correspondence and reports.

(d) *Timing of data release.* CMS will release MA bid pricing data as provided in paragraph (b) of this section on an annual basis after the first Monday in October.

[81 FR 80556, Nov. 15, 2016]

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 1106, 1128J(d), 1852, 1853, 1854, and 1858 of the Act. It sets forth the requirements for making payments to MA organizations offering local and regional MA policies, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), collection of risk adjustment data, conditions for use and disclosure of risk adjustment data, collection of improper payments and other payment rules. Section 422.458 specifies the requirements for risk sharing payments to MA regional organizations.

[88 FR 6665, Feb. 1, 2023]

§ 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.

(f) *Separate payment for meaningful use of certified EHRs.* In the case of qualifying MA organizations, as defined in § 495.200 of this chapter, entitled to MA EHR incentive payments per § 495.204 of this chapter, such payments are made in accordance with sections 1853(l) and (m) of the Act and subpart C of part 495 of this chapter.

[70 FR 4729, Jan. 28, 2005, as amended at 75 FR 44564, July 28, 2010; 85 FR 72909, Nov. 16, 2020]

§ 422.306 Annual MA capitation rates.

Subject to adjustments at §§ 422.308(b) and (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, and is then adjusted to exclude the applicable phase-in percentage of the standardized costs for payments under section 1886(d)(5)(B) of the Act in the area for the year under paragraph (c) of this section and costs for kidney acquisitions in the area for the year under paragraph (d) 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 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;

(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; and

(iv) Adjusted to exclude costs attributable to payments under sections 1848(o) and 1886(n) of the Act of Medicare FFS incentive payments for meaningful use of electronic health records.

(c) *Phase-out of the indirect costs of medical education from MA capitation rates.* Beginning with 2010, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b), the amount is adjusted in accordance with section 1853(k)(4) of the Act to exclude from such amount the phase-in percentage for the year of the estimated costs for payments under section 1886(d)(5)(B) of the Act in the area for the year.

(d) *Exclusion of costs for kidney acquisitions from MA capitation rates.* Beginning with 2021, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b) of this section, the amount is adjusted in accordance with section 1853(k)(5) of the Act to exclude the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d) of the Act) in the area for the year.

[70 FR 4729, Jan. 28, 2005, as amended at 73 FR 54250, Sept. 18, 2008; 75 FR 19806, Apr. 15, 2010; 75 FR 44564, July 28, 2010; 85 FR 33907, June 2, 2020]

§ 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.* (1) 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.

(2) The amount calculated in paragraph (a)(1) of this section must exclude expenditures attributable to sections 1848(a)(7) and (o) and sections 1886(b)(3)(B)(ix) and (n) of the Act.

(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.

(4) *Authority to apply frailty adjustment under PACE payment rules for certain specialized MA plans for special needs individuals.* (i) *Application of payment rules.* For plan year 2011 and subsequent plan years, in the case of a plan described in paragraph (c)(4)(ii) of this section, the Secretary may apply the payment rules under section 1894(d) of the Act (other than paragraph (3) of that section) rather than the payment rules that would otherwise apply under this part, but only to the extent necessary to reflect the costs of treating high concentrations of frail individuals.

(ii) *Plan described.* A plan described in this paragraph is a fully integrated dual-eligible special needs plan, as defined at § 422.2, and has a similar average level of frailty (as determined by the Secretary) as the PACE program.

(5) *Application of coding adjustment.* (i) In applying the adjustment under paragraph (c)(1) of this section for health status to payment amounts, the Secretary ensures that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between MA plans and providers under Part A and B to the extent that the Secretary has identified such differences.

(ii) In order to ensure payment accuracy, the Secretary annually conducts an analysis of the differences described in paragraph (c)(5)(i) of this section.

(A) The Secretary completes such analysis by a date necessary to ensure that the results of such analysis are incorporated on a timely basis into the risk scores for 2008 and subsequent years.

(B) In conducting such analysis, the Secretary uses data submitted with respect to 2004 and subsequent years, as available and updated as appropriate.

(iii) In calculating each year's adjustment, the adjustment factor is as follows:

(A) For 2014, not less than the adjustment factor applied for 2010, plus 1.3 percentage points.

(B) For each of the years 2015 through 2018, not less than the adjustment factor applied for the previous year, plus 0.25 percentage points.

(C) For 2019 and each subsequent year, not less than 5.7 percent.

(iv) Such adjustment is applied to risk scores until the Secretary implements risk adjustment using MA diagnostic, cost, and use data.

(6) *Improvements to risk adjustment for special needs individuals with chronic health conditions*—(i) *General rule.* For 2011 and subsequent years, for purposes of the adjustment under paragraph (c)(1) of this section with respect to individuals described in paragraph (c)(6)(ii) of the section, the Secretary uses a risk score that reflects the known underlying risk profile and chronic health status of similar individuals. Such risk score is used instead of the default risk score for new enrollees in MA plans that are not specialized MA plans for special needs individuals (as defined in section 1859(b)(6) of the Act).

(ii) *Individuals described.* An individual described in this clause is a special needs individual described in section 1859(b)(6)(B)(iii) of the Act who enrolls in a specialized MA plan for special needs individuals on or after January 1, 2011.

(iii) *Evaluation.* For 2011 and periodically thereafter, the Secretary evaluates and revises the risk adjustment system under this paragraph in order to, as accurately as possible, account for—

(A) Higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness; and

(B) Costs that may be associated with higher concentrations of beneficiaries with the conditions specified in paragraph (c)(6)(iii)(A) of this section.

(iv) *Publication of evaluation and revisions.* The Secretary publishes, as part of an announcement under section 1853(b) of the Act, a description of any evaluation conducted under paragraph (c)(6)(iii) of this section during the preceding year and any revisions made under paragraph (c)(6)(iii) of this section as a result of such evaluation.

(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.

[70 FR 4729, Jan. 28, 2005, as amended at 75 FR 44564, July 28, 2010; 76 FR 21567, Apr. 15, 2011]

§ 422.310 Risk adjustment data.

(a) *Definition of risk adjustment data.* Risk adjustment data are all data that are used in the development and 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 item and 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) Items and services covered under the original Medicare program.

(ii) Medicare covered items and 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 CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards. CMS may specify abbreviated formats for data submission required of MA organizations.

(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 item or service.

(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.

(5) For data described in paragraph (d)(1) of this section as data equivalent to Medicare fee-for-service data, which is also known as MA encounter data, MA organizations must submit a NPI in a billing provider field on each MA

encounter data record, per CMS guidance.

(e) *Validation of risk adjustment data.* MA organizations and their providers and practitioners are 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. MA organizations must remit improper payments based on RADV audits, in a manner specified by CMS. For RADV audits, CMS may extrapolate RADV Contract-Level audit findings for payment year 2018 and subsequent payment years.

(f) *Use and release of data*—(1) *CMS use of data.* CMS may use the data described in paragraphs (a) through (d) of this section for the following purposes:

(i) To determine the risk adjustment factors used to adjust payments, as required under §§ 422.304(a) and (c);

(ii) To update risk adjustment models;

(iii) To calculate Medicare DSH percentages;

(iv) To conduct quality review and improvement activities;

(v) For Medicare coverage purposes;

(vi) To conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research;

(vii) For activities to support the administration of the Medicare program;

(viii) For activities conducted to support program integrity; and

(ix) For purposes authorized by other applicable laws.

(2) *CMS release of data.* Regarding data described in paragraphs (a) through (d) of this section, CMS may release the minimum data it determines is necessary for one or more of the purposes listed in paragraph (f)(1) of this section to other HHS agencies, other Federal executive branch agencies, States, and external entities in accordance with the following:

(i) Applicable Federal laws;

(ii) CMS data sharing procedures;

(iii) Subject to the protection of beneficiary identifier elements and beneficiary confidentiality, including—

(A) A prohibition against public disclosure of beneficiary identifying information;

(B) Release of beneficiary identifying information to other HHS agencies, other Federal executive branch agencies, and States only when such information is needed; and

(C) Release of beneficiary identifying information to external entities only to the extent needed to link datasets.

(iv) Subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data.

(v) Risk adjustment data other than data described in paragraphs (f)(2)(iii) and (f)(2)(iv) of this section will be released without the redaction or aggregation described in paragraphs (f)(2)(iii) and (f)(2)(iv) of this section, respectively.

(3) Risk adjustment data will not become available for release under this paragraph (f) unless—

(i) The risk adjustment reconciliation for the applicable payment year has been completed;

(ii) CMS determines that data release is necessary under paragraph (f)(1)(vi) of this section for emergency preparedness purposes before reconciliation; or

(iii) CMS determines that extraordinary circumstances exist to release the data before reconciliation.

(g) *Deadlines for submission of risk adjustment data.* Risk adjustment factors for each payment year are based on risk adjustment data submitted for items and 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. CMS may adjust these deadlines, as appropriate.

(1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting items and 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) After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary.

(i) Prior to calculation of final risk factors for a payment year, CMS allows a reconciliation process to account for risk adjustment data submitted after the March deadline until the final risk adjustment data submission deadline in the year following the payment year.

(ii) After the final risk adjustment data submission deadline, which is a date announced by CMS that is no earlier than January 31 of the year following the payment year, an MA organization can submit data to correct overpayments but cannot submit diagnoses for additional payment.

(3) Submission of corrected risk adjustment data in accordance with overpayments after the final risk adjustment data submission deadline, as described in paragraph (g)(2) of this section, must be made as provided in § 422.326.

[73 FR 48757, Aug. 19, 2008, as amended at 79 FR 29956, May 23, 2014; 79 FR 50358, Aug. 22, 2014; 80 FR 7960, Feb. 12, 2015; 83 FR 16733, Apr. 16, 2018; 88 FR 6665, Feb. 1, 2023]

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.

(1) Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary's payment error extrapolation and recovery methodologies.

(2) CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years.

(b) *RADV audit results.* (1) MA organizations that undergo RADV audits will be issued an audit report post medical record review that describes the results of the RADV audit as follows:

(i) Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies.

(ii) The contract-level RADV payment error estimate in dollars.

(iii) The contract-level payment adjustment amount to be made in dollars.

(iv) An approximate timeframe for the payment adjustment.

(v) A description of the MA organization's RADV audit appeal rights.

(2) *Compliance date.* The compliance date for meeting RADV medical record submission requirements for the validation of risk adjustment data is the due date when MA organizations selected for RADV audit must submit medical records to the Secretary.

(c) *RADV audit appeals*—(1) *Appeal rights.* MA organizations that do not agree with their RADV audit results may appeal.

(2) *Issues eligible for RADV appeals*—(i) *General rules.* MA organizations may appeal RADV medical record review determinations and the Secretary's RADV payment error calculation. In order to be eligible for RADV appeal, MA organizations must adhere to the following:

(A) Established RADV audit procedures and requirements.

(B) RADV appeals procedures and requirements.

(ii) *Failure to follow RADV rules.* Failure to follow the Secretary's RADV audit procedures and requirements and the Secretary's RADV appeals procedures and requirements will render the MA organization's request for appeal invalid.

(iii) *RADV appeal rules.* The MA organization's written request for medical record review determination appeal must specify the following:

(A) The audited HCC(s) that the Secretary identified as being in error.

(B) A justification in support of the audited HCC selected for appeal.

(iv) *Number of medical records eligible for appeal.* For each audited HCC, MA organizations may appeal one medical record that has undergone RADV review. If an attestation was submitted to cure a signature or credential-related error, the attestation may be included in the HCC appeal.

(v) *Selection of medical record for appeal.* The MA organization must select the medical record that undergoes appeal.

(vi) *Written request for RADV payment error calculation appeal.* The written request for RADV payment error calculation appeal must clearly specify the following:

(A) The MA organization's own RADV payment error calculation.

(B) Where the Secretary's RADV payment error calculation was erroneous.

(3) *Issues ineligible for RADV appeals.* (i) MA organizations' request for appeal may not include HCCs, medical records or other documents beyond the audited HCC, RADV-reviewed medical record, and any accompanying attestation that the MA organization chooses for appeal.

(ii) MA organizations may not appeal the Secretary's medical record review determination methodology or RADV payment error calculation methodology.

(iii) As part of the RADV payment error calculation appeal— MA organizations may not appeal RADV medical record review-related errors.

(iv) MA organizations may not appeal RADV errors that result from an MA organization's failure to submit a medical record.

(4) *Burden of proof.* The MA organization bears the burden of proof by a preponderance of the evidence in demonstrating that the Secretary's medical record review determination(s) or payment error calculation was incorrect.

(5) *Manner and timing of a request for RADV appeal.* (i) At the time the Secretary issues its RADV audit report, the Secretary notifies audited MA organizations of the following:

(A) That they may appeal RADV HCC errors that are eligible for medical record review determination appeal.

(B) That they may appeal the Secretary's RADV payment error calculation.

(ii) MA organizations have 60 days from date of issuance of the RADV audit report to file a written request with CMS for RADV appeal. This request for RADV appeal must specify one of the following:

(A) Whether the MA organization requests medical record review determination appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(B) Whether the MA organization requests RADV payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(C) Whether the MA organization requests both medical record review determination appeal and RADV payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(iii) For MA organizations that appeal both medical record review determination appeal and RADV payment error calculation appeal:

(A) The Secretary adjudicates the request for RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal.

(B) An MA organization's request for appeal of its RADV payment error calculation will not be adjudicated until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final for that stage of appeal.

(6) *Reconsideration stage*—(i) *Written request for medical record review reconsideration.* A MA organization's written request for medical record review determination reconsideration must specify the following:

(A) The audited HCC that the Secretary identified as being in error that the MA organization wishes to appeal.

(B) A justification in support of the audited HCC chosen for appeal.

(ii) *Written request for payment error calculation.* The MA organization's written request for payment error calculation reconsideration—

(A) Must include the MA organization's own RADV payment error calculation that clearly specifies where the Secretary's RADV payment error calculation was erroneous; and

(B) May include additional documentary evidence pertaining to the calculation of the payment error that the MA organization wishes the reconsideration official to consider.

(iii) *Conduct of the reconsideration.* (A) For medical record review determination reconsideration, a medical record review professional who was not involved in the initial medical record review determination of the disputed audited HCCs does the following:

(*1*) Reviews the medical record and accompanying dispute justification.

(*2*) Reconsiders the initial audited medical record review determination.

(B) For payment error calculation reconsideration, CMS ensures that a third party not involved in the initial RADV payment error calculation does the following:

(*1*) Reviews the Secretary's RADV payment error calculation.

(*2*) Reviews the MA organization's RADV payment error calculation;

(*3*) Recalculates the payment error in accordance with CMS's RADV payment error calculation procedures.

(iv) *Effect of the reconsideration official's decision*. (A) The reconsideration official issues a written reconsideration decision to the MA organization.

(B) The reconsideration official's decision is final unless the MA organization disagrees with the reconsideration official's decision.

(C) If the MA organization disagrees with the reconsideration official's decision, they may request a hearing in accordance with paragraph (c)(7) of this section.

(7) *Hearing stage*—(i) *Errors eligible for hearing*. At the time the reconsideration official issues his or her reconsideration determination to the MA organization, the reconsideration official notifies the MA organization of any RADV HCC errors or payment error-calculations that are eligible for RADV hearing.

(ii) *General hearing rules*. A MA organization that requests a RADV hearing must do so in writing in accordance with procedures established by CMS.

(iii) *Written request for hearing*. The written request for a hearing must be filed with the Hearing Officer within 60 days of the date the MA organization receives the reconsideration officer's written reconsideration decision.

(A) If the MA organization appeals medical record review reconsideration determination, the written request for RADV hearing must—

(*1*) Include a copy of the written decision of the reconsideration official;

(*2*) Specify the audited HCCs that the reconsideration official confirmed as being in error; and

(*3*) Specify a justification why the MA organization disputes the reconsideration official's determination.

(B) If the MA organization appeals the RADV payment error calculation reconsideration determination, the written request for RADV hearing must include the following:

(*1*) A copy of the written decision of the reconsideration official.

(*2*) The MA organization's own RADV payment error calculation that clearly specifies where the Secretary's payment error calculation was erroneous.

(iv) *Designation of hearing officer*. A hearing officer will conduct the RADV hearing.

(v) *Disqualification of the 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.

(D) If the hearing officer withdraws, another hearing officer conducts the hearing.

(E) 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 the Secretary.

(vi) *Hearing Officer review*. The hearing officer reviews the following:

(A) For a medical record review determination appeal, the hearing officer reviews all of the following:

(*1*) The RADV-reviewed medical record and any accompanying attestation that the MA organization selected for review.

(*2*) The reconsideration official's written determination.

(*3*) The written brief submitted by the MA organization or the Secretary in response to the reconsideration official's determination.

(B) For a payment error calculation appeal, the hearing officer reviews all of the following:

(*1*) The reconsideration official's written determination.

(*2*) Briefs addressing the reconsideration decision.

(vii) *Hearing procedures*—(A) *Authority of the Hearing Officer*. The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and the Secretary rulings. These powers include the authority to dismiss the appeal with prejudice and take any other action which the hearing officer considers appropriate, including for failure to comply with such rules and procedures.

(B) *The hearing is on the record*. (*1*) Except as specified in paragraph (c)(viii)(B)(*2*) of this section, the hearing officer is limited to the review of the record.

(*2*)(*i*) Subject to the hearing officer's full discretion, the parties may request a live or telephonic hearing regarding some or all of the disputed medical records.

(*ii*) The hearing officer may, on his or her own-motion, schedule a live or telephonic hearing.

(*3*) The record is comprised of the following:

(*i*) *Written decisions* described at paragraphs (c)(6)(iv) and (7)(vi) of this section.

(*ii*) Written briefs from the MA organization explaining why they believe the reconsideration official's determination was incorrect.

(*iii*) The Secretary's optional brief that responds to the MA organization's brief—

(*4*) The hearing officer neither receives testimony nor accepts any new evidence that is not part of the record.

(*5*) Either the MA organization or the Secretary may ask the hearing officer to rule on a motion for summary judgment.

(viii) *Hearing Officer decision*. The hearing officer decides whether to uphold or overturn the reconsideration official's decision, and sends a written determination to CMS and the MA organization, explaining the basis for the decision.

(ix) *Computations based on hearing decision*. (A) Once the hearing officer's decision is considered final in accordance with paragraph (c)(7)(x) of this section, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS.

(B) For MA organizations appealing the RADV error calculation only, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS.

(x) *Effect of the Hearing Officer's decision*. The hearing officer's decision is final unless the decision is reversed or modified by the CMS Administrator.

(8) *CMS Administrator review stage*. (i) A request for CMS Administrator review must be made in writing and filed with the CMS Administrator.

(ii) CMS or a MA organization that has received a hearing officer's decision and requests review by the CMS Administrator must do so within 60 days of receipt of the hearing officer's decision.

(iii) After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision.

(iv) If the CMS Administrator elects to review the hearing decision—

(A) The CMS Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the notification; and

(B) The CMS Administrator is limited to the review of the record. The record is comprised of the following:

(*1*) The record is comprised of documents described at paragraph (c)(7)(vii)(B)(3) of this section.

(*2*) The hearing record.

(*3*) Written arguments from the MA organization or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect.

(C) The CMS Administrator reviews the record and determines whether the hearing officer's determination should be upheld, reversed, or modified.

(v) The CMS Administrator renders his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision.

(vi) The decision of the hearing officer is final if the CMS Administrator—

(A) Declines to review the hearing officer's decision; or

(B) Does not make a decision within 60 days.

[75 FR 19806, Apr. 15, 2010; 75 FR 32859, June 10, 2010; as amended at 79 FR 29956, May 23, 2014; 88 FR 6665, Feb. 1, 2023]

§ 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 60 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 30 days to comment on the proposed changes.

[70 FR 4729, Jan. 28, 2005, as amended at 85 FR 33908, June 2, 2020]

§ 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.

(3) Payments under subpart C of part 495 of this chapter for meaningful use of certified EHR technology are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. In applying section 1848(o) of the Act under sections 1853(l) and 1886(n)(2)of the Act under section 1853(m) of the Act, CMS determines the amount to the extent feasible and practical to be similar to the estimated amount in the aggregate that would be payable for services furnished by professionals and hospitals under Parts B and A, respectively, under title XVIII of the Act.

(b) *Payments to the MA organization.* Subject to §§ 412.105(g), 413.76, and 495.204 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.

(d) *FFS payment for expenses for kidney acquisitions.* Paragraphs (b) and (c) of this section do not apply with respect to expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005; 75 FR 44654, July 28, 2010; 85 FR 33908, June 2, 2020; 85 FR 72909, Nov. 16, 2020]

§ 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 § 413.75(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.

[70 FR 4729, Jan. 28, 2005, as amended at 85 FR 72909, Nov. 16, 2020]

§ 422.326 Reporting and returning of overpayments.

(a) *Terminology*. For purposes of this section—

Applicable reconciliation occurs on the date of the annual final deadline for risk adjustment data submission described at § 422.310(g), which is announced by CMS each year.

Funds means any payment that an MA organization has received that is based on data submitted by the MA organization to CMS for payment purposes, including § 422.308(f) and § 422.310.

Overpayment means any funds that an MA organization has received or retained under title XVIII of the Act to which the MA organization, after applicable reconciliation, is not entitled under such title.

(b) *General rule*. If an MA organization has identified that it has received an overpayment, the MA organization must report and return that overpayment in the form and manner set forth in this section.

(c) *Identified overpayment*. The MA organization has identified an overpayment when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment.

(d) *Reporting and returning of an overpayment*. An MA organization must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment, unless otherwise directed by CMS for purposes of § 422.311.

(1) *Reporting*. An MA organization must notify CMS, of the amount and reason for the overpayment, using a notification process determined by CMS.

(2) *Returning*. An MA organization must return identified overpayments in a manner specified by CMS.

(e) *Enforcement*. Any overpayment retained by an MA organization is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) of this section.

(f) *Look-back period*. An MA organization must report and return any overpayment identified for the 6 most recent completed payment years.

[79 FR 29958, May 23, 2014]

§ 422.330 CMS-identified overpayments associated with payment data submitted by MA organizations.

(a) *Definitions*. For purposes of this section—

Applicable reconciliation date occurs on the date of the annual final deadline for risk adjustment data submission described at § 422.310(g)(2)(ii).

Erroneous payment data means payment data that should not have been submitted either because the data submitted are inaccurate or because the data are inconsistent with Medicare Part C requirements.

Payment data means data submitted by an MA organization to CMS and used for payment purposes, including

enrollment data and data submitted under § 422.310.

(b) *Request to correct payment data.* (1) When CMS identifies erroneous payment data submitted by an MA organization (other than an error identified through the process described in § 422.311), CMS may send a data correction notice to the MA organization requesting that the MA organization correct the payment data.

(2) The notice will include or make reference to the specific payment data that need to be corrected, the reason why CMS believes that the payment data are erroneous, and the timeframe for correcting the payment data.

(c) *Payment offset.* (1) If the MA organization fails to submit the corrected payment data within the timeframe as requested in accordance with paragraph (b) of this section, CMS will conduct a payment offset against payments made to the MA organization if—

(i) The payment error affects payments for any of the 6 most recently completed payment years; and

(ii) The payment error for a particular payment year is identified after the applicable reconciliation date for that payment year.

(2) CMS will calculate the payment offset amount using the correct payment data and a payment algorithm that applies the payment rules for the applicable year.

(d) *Payment offset notification.* CMS will issue a payment offset notice to the MA organization that includes at least the following:

(1) The dollar amount of the offset from plan payments.

(2) An explanation of how the erroneous data were identified and used to calculate the payment offset amount.

(3) An explanation that, if the MA organization disagrees with the payment offset, it may request an appeal within 30 days of issuance of the payment offset notification.

(e) *Appeals process.* If an MA organization does not agree with the payment offset described in paragraph (c) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* An MA organization may request reconsideration of the payment offset described in paragraph (c) of this section, according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 30 days from the date that CMS issued the payment offset notice to the MA organization.

(ii) *Content of request.* The written request for reconsideration must specify the findings or issues with which the MA organization disagrees and the reasons for its disagreement. As part of its request for reconsideration, the MA organization may include any additional documentary evidence in support of its position. Any additional evidence must be submitted with the request for reconsideration. Additional information submitted after this time will be rejected as untimely.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the underlying data that were used to determine the amount of the payment offset and any additional documentary evidence timely submitted by the MA organization.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the MA organization of its decision on the reconsideration request.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (e)(2) of this section.

(2) *Informal hearing.* An MA organization dissatisfied with CMS' reconsideration decision made under paragraph (e)(1) of this section is entitled to an informal hearing as provided for under paragraphs (e)(2)(i) through (e)(2)(v) of this section.

(i) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with CMS within 30 days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the MA organization disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing will be conducted in accordance with the following:

(A) CMS provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) The informal hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not timely presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before the CMS reconsideration official when CMS made its reconsideration determination.

(C) The CMS hearing officer will review the proceeding before the CMS reconsideration official on the record made before the CMS reconsideration official using the clearly erroneous standard of review.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the MA organization explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (e)(3) of this section.

(3) *Review by the Administrator.* The Administrator review will be conducted in the following manner:

(i) An MA organization that has received a hearing officer's decision may request review by the Administrator within 30 days of the date of issuance of the hearing officer's decision under paragraph (e)(2)(iv) of this section. The MA organization may submit written arguments to the Administrator for review.

(ii) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (e)(3)(iv) of this section or to decline to review the hearing officer's decision.

(iii) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iv) If the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(v) The Administrator's determination is final and binding.

(f) *Matters subject to appeal and burden of proof.* (1) The MA organization's appeal is limited to CMS' finding that the payment data submitted by the MA organization are erroneous.

(2) The MA organization bears the burden of proof by a preponderance of the evidence in demonstrating that CMS' finding that the payment data were erroneous was incorrect or otherwise inconsistent with applicable program requirements.

(g) *Applicability of appeals process.* The appeals process under paragraph (e) of this section applies only to payment offsets under paragraph (c) of this section.

[79 FR 67031, Nov. 10, 2014]

Subpart H—Provider-Sponsored Organizations

EDITORIAL NOTE: Nomenclature changes to subpart H of part 422 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 collectible 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.

[70 FR 4732, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005; 76 FR 21568, Apr. 15, 2011]

Subpart K—Application Procedures and Contracts for 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, including MA organizations offering a specialized MA plan for special needs individuals. 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.

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services are excluded, when determining inappropriate prescribing. Plan sponsors may consider any number of factors including, but not limited to the following:

(1) Documentation of a patient's medical condition.

(2) Identified instances of patient harm or death.

(3) Medical records, including claims (if available).

(4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(5) Levels of morphine milligram equivalent (MME) dosages prescribed.

(6) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

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.

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier—

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

[63 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; 77 FR 22167, Apr. 12, 2012; 86 FR 6098, Jan. 19, 2021]

§ 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 and additional application requirements for MA organizations seeking to offer a Specialized MA Plan for Special Needs Individuals.

(b) *Completion of a notice of intent to apply.* (1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not first submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(3) An organization's decision not to submit an application after submitting a Notice of Intent To Apply will not form the basis of any action taken against the organization by CMS.

(c) *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 fully complete all parts of 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.

(ii) For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.

(iii) For Specialized MA Plans for Special Needs Individuals, documentation that the entity meets the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

(iv) Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.

(d) *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.

(e) *Resubmittal of an application.* An application that has been denied by CMS for a particular contract year may not be resubmitted until the beginning of the application cycle for the following contract year.

(f) *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, as amended at 75 FR 19809, Apr. 15, 2010; 77 FR 22167, Apr. 12, 2012; 81 FR 80557, Nov. 15, 2016; 83 FR 16733, Apr. 16, 2018]

§ 422.502 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an application for an MA contract or for a Specialized MA Plan for Special Needs Individuals solely 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.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part.

(b) *Use of information from a current or prior contract.* (1) Except as provided in paragraphs (b)(2) through (4) of this section, if an MA organization fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial

under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees in accordance with § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(b)(14).

(C) Filed for or is currently in State bankruptcy proceedings.

(D) Received any combination of Part C or D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in § 422.166.

(E) Met or exceeded 13 points for compliance actions for any one contract.

(*1*) CMS determines the number of points each MA organization accumulated during the performance period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued during the performance period under § 422.504(m) counts for 6 points.

(*ii*) Each warning letter issued during the performance period under § 422.504(m) counts for 3 points.

(*iii*) Each notice of noncompliance issued during the performance period under § 422.504(m) counts for 1 point.

(*2*) CMS adds all the point values for each MA organization to determine if any organization meets CMS' identified threshold.

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part, with the exception of a sanction imposed under § 422.752(d) or a determination by CMS to prohibit the enrollment of new enrollees pursuant to § 422.2410(c).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(b)(14).

(ii) CMS may deny an application submitted by an organization that does not hold a Part C contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section. This paragraph does not apply when the parent organization completed the acquisition of the subsidiary that meets the criteria within the 24 months preceding the application submission deadline.

(2) In the absence of 12 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program.

(3) If CMS has terminated, under § 422.510, or non-renewed, under § 422.506(b), an MA organization's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application for a new contract or service area expansion based on the applicant's substantial failure to comply with the requirements of the Part C program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(c) *Notice of determination.* Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract or to be designated a Specialized MA Plan for Special Needs Individuals 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 or Specialized MA Plan for Special Needs Individuals, CMS gives the applicant notice of intent to deny the application for an MA contract or for a Specialized MA Plan for Special Needs Individuals a summary of the basis for this preliminary finding.

(ii) Within 10 days from the intent to deny, the 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.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

(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 and/or is not qualified to offer a Specialized MA Plan for Special Needs Individuals;

(ii) The reasons why the applicant is not qualified; and

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

[70 FR 4736, Jan. 28, 2005, as amended at 75 FR 19809, Apr. 15, 2010; 76 FR 21568, Apr. 15, 2011; 77 FR 22167, Apr. 12, 2012; 80 FR 7960, Feb. 12, 2015; 83 FR 16733, Apr. 16, 2018; 86 FR 6099, Jan. 19, 2021; 87 FR 27896, May 9, 2022]

§ 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 communication 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) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS'

program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(*1*) Articulate the organization's commitment to comply with all applicable Federal and State standards;

(*2*) Describe compliance expectations as embodied in the standards of conduct;

(*3*) Implement the operation of the compliance program;

(*4*) Provide guidance to employees and others on dealing with potential compliance issues;

(*5*) Identify how to communicate compliance issues to appropriate compliance personnel;

(*6*) Describe how potential compliance issues are investigated and resolved by the organization; and

(*7*) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee who report directly and are accountable to the organization's chief executive or other senior management.

(*1*) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the MA organization, parent organization or corporate affiliate. The compliance officer may not be an employee of the MA organization's first tier, downstream or related entity.

(*2*) The compliance officer and the compliance committee must periodically report directly to the governing body of the MA organization on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(*3*) The governing body of the MA organization must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(*1*) Each MA organization must establish and implement effective training and education for its compliance officer and organization employees, the MA organization's chief executive and other senior administrators, managers and governing body members.

(*2*) Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee and new appointment to a chief executive, manager, or governing body member.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the MA organization's employees, managers and governing body, and the MA organization's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that—

(*1*) Articulate expectations for reporting compliance issues and assist in their resolution,

(*2*) Identify noncompliance or unethical behavior; and

(*3*) Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance

issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(*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.

(*3*) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

(*4*) The MA organization must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan related to the inappropriate prescribing of opioids.

(*5*) The MA organization must submit data, as specified in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the MA organization; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data categories, as applicable, include referral information and actions taken by the MA organization on the referral.

(*6*)(*i*) The MA organization is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*)(*i*) of this section 7 days prior to implementation of the payment suspension. The MA organization may request an exception to the 7-day prior notification to the Secretary, or its designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

(*ii*) The MA organization is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 30, 2022), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31).

(*7*)(*i*) CMS will provide MA organizations with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)(*i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2022), that the report reflect

the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 30, 2022.

(5) Not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(i) Not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

(ii) Not accept, or be either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs 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.

(7) Not have terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c) of this subpart.

(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.

(iv) CMS may require that the MA organization hire an independent auditor to provide CMS with additional information to determine if deficiencies found during an audit or inspection have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(e) *Severability of contracts.* The contract must provide that, upon CMS's request—

(1) The contract will be amended to exclude any MA plan, MA plan segment, or State-licensed entity specified by CMS; and

(2) A separate contract for any such excluded plan, segment, 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; 72 FR 68722, Dec. 5, 2007; 75 FR 19809, Apr. 15, 2010; 79 FR 29958, May 23, 2014; 80 FR 7960, Feb. 12, 2015; 83 FR 16733, Apr. 16, 2018; 86 FR 6099, Jan. 19, 2021; 87 FR 27896, May 9, 2022; 88 FR 22334, Apr. 12, 2023]

§ 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. Compliance with the terms of this paragraph (a) is material to the performance of the MA 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 and supplier 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, limits on physician incentive plans, and the preclusion list requirements in §§ 422.222 and 422.224.

(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) Maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

(15) Through the CMS complaint tracking system, to address and resolve complaints received by CMS against the MA organization.

(16) To maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality improvement activities related to the delivery of Part C services.

(17) To maintain a Part C summary plan rating score of at least 3 stars under the 5-star rating system specified in subpart D of this part. A Part C summary plan rating is calculated as provided in § 422.166.

(18) To comply with the requirements for access to health data and plan information under §§ 422.119 and 422.120 of this chapter.

(19) Not to establish a segment of an MA plan that meets the criteria in § 422.514(d), as determined in the procedures described in § 422.514(e)(3), with the addition of the newly enrolled individuals.

(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, audit, or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) Compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the MA organization to include computer and other electronic systems; and

(iv) 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) Effective January 1, 2010, 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 enrollee liable for payment of any such fees;

(ii) Indemnify the 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 enrollees; and

(iii) For all MA organizations with enrollees eligible for both Medicare and Medicaid, specify in contracts with providers that such enrollees will not be held liable for Medicare Part A and B cost sharing when the State is responsible for paying such amounts, and inform providers of Medicare and Medicaid benefits, and rules for enrollees eligible for Medicare and Medicaid. The MA plans may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such a plan. The contracts must state that providers will—

(A) Accept the MA plan payment as payment in full, or

(B) Bill the appropriate State source.

(iv) Ensure that the enrollee does not have any financial liability for services, items, or drugs furnished, ordered, or prescribed to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222.

(v) Ensure that the plan's provider agreement contains a provision stating that after the expiration of the 60-day period specified in § 422.222:

(A) The provider will no longer be eligible for payment from the plan and will be prohibited from pursuing payment from the beneficiary as stipulated by the terms of the contract between CMS and the plan per § 422.504(g)(1)(iv); and

(B) The provider will hold financial liability for services, items, and drugs that are furnished, ordered, or prescribed after this 60-day period, at which point the provider and the beneficiary will have already received notification of the preclusion.

(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 first tier, downstream, and related entities.* (1) Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, 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 first tier, downstream, and related entities to agree that—

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and entities related to CMS' contract with the MA organization.

(ii) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records under paragraph (i)(2)(i) of this section directly from any first tier, downstream, or related entity.

(iii) For records subject to review under paragraph (i)(2)(ii) of this section, except in exceptional circumstances, CMS will provide notification to the MA organization that a direct request for information has been initiated.

(iv) 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.

(v) They will ensure that payments are not made to individuals and entities included on the preclusion list, defined in § 422.2.

(3) All contracts or written arrangements between MA organizations and first tier, downstream, and related 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 first tier, downstream, or related entity, 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 first tier, downstream, and related entity in accordance with a contract 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 first tier, downstream and related entity:

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract 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) Each and every contract must specify that the performance of the parties is monitored by the MA organization on an ongoing basis.

(iv) Each and every contract 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 contract 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.

(5) *Certification of accuracy of data for overpayments.* The CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that the information provided for purposes of reporting and returning of overpayments under §422.326 is accurate, complete, and truthful.

(m) *Issuance of compliance actions for failure to comply with the terms of the contract.* The MA organization acknowledges that CMS may take compliance actions as described in this section or intermediate sanctions as defined in subpart O of this part.

(1) CMS may take compliance actions as described in paragraph (m)(3) of this section if it determines that the MA organization has not complied with the terms of a current or prior Part C contract with CMS.

(i) CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations in this chapter, or guidance.

(ii) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that an MA organization is out of compliance when its performance in fulfilling Part C requirements represents an outlier relative to the performance of other MA organizations.

(2) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(i) The nature of the conduct.

(ii) The degree of culpability of the MA organization.

(iii) The adverse effect to beneficiaries which resulted or could have resulted from the conduct of the MA organization.

(iv) The history of prior offenses by the MA organization or its related entities.

(v) Whether the noncompliance was self-reported.

(vi) Other factors which relate to the impact of the underlying noncompliance or the lack of the MA organization's oversight of its operations that contributed to the noncompliance.

(3) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(i) *Notice of noncompliance.* A notice of noncompliance may be issued for any failure to comply with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section.

(ii) *Warning letter.* A warning letter may be issued for serious and/or continued noncompliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(iii) *Corrective action plan.* (A) Corrective action plans are requested for particularly serious or continued noncompliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(B) CMS issues a corrective action plan if CMS determines that the MA organization has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance, or must implement a detailed plan to correct the underlying causes of the noncompliance.

(n) *Acknowledgements of CMS release of data*—(1) *Summary CMS payment data.* The contract must provide that the MA organization acknowledges that CMS releases to the public summary reconciled CMS payment data after the reconciliation of Part C and Part D payments for the contract year as follows:

(i) For Part C, the following data—

(A) Average per member per month CMS payment amount for A/B (original Medicare) benefits for each MA plan offered, standardized to the 1.0 (average risk score) beneficiary.

(B) Average per member per month CMS rebate payment amount for each MA plan offered (or, in the case of MSA plans, the monthly MSA deposit amount).

(C) Average Part C risk score for each MA plan offered.

(D) County level average per member per month CMS payment amount for each plan type in that county, weighted by enrollment and standardized to the 1.0 (average risk score) beneficiary in that county.

(ii) For Part D plan sponsors, plan payment data in accordance with § 423.505(o) of this subchapter.

(2) *MA bid pricing data and Part C MLR data.* The contract must provide that the MA organization acknowledges that CMS releases to the public data as described at §§ 422.272 and 422.2490.

(o) *Business continuity.* (1) The MA organization agrees to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. To meet the requirement, the business continuity plan must, at a minimum, include the following:

(i) *Risk assessment.* Identify threats and vulnerabilities that might affect business operations.

(ii) *Mitigation strategy.* Design strategies to mitigate hazards. Identify essential functions in addition to those specified in paragraph (o)(2) of this section and prioritize the order in which to restore all other functions to normal operations. At a minimum, each MA organization must do the following:

(A) Identify specific events that will activate the business continuity plan.

(B) Develop a contingency plan to maintain, during any business disruption, the availability and, as applicable, confidentiality of communication systems and essential records in all forms (including electronic and paper copies). The contingency plan must do the following:

(*1*) Ensure that during any business disruption the following systems will operate continuously or, should they fail, be restored to operational capacity on a timely basis:

(*i*) Information technology (IT) systems including those supporting claims processing at point of service.

(*ii*) Provider and enrollee communication systems including telephone, Web site, and email.

(*2*) With respect to electronic protected health information, comply with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 Security Regulations at 45 CFR parts 160 and 164, subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(*1*) Employees.

(*2*) First tier, downstream, and related entities.

(*3*) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate appropriate employees about the business continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraphs (o)(1)(i) through (iv) of this section.

(B) Make the information specified in paragraph (o)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every MA organization must plan to restore essential functions within 72 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential functions that the MA organization identifies under paragraph (o)(1)(ii) of this section, for purposes of this paragraph (o)(2) of the section essential functions include, at a minimum, the following:

(i) Benefit authorization (if not waived) for services to be immediately furnished at a hospital, clinic, provider office, or other place of service.

(ii) Operation of call center customer services.

[63 FR 35099, June 26, 1998]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 422.504, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

§ 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 the MA organization has not provided CMS with a notice of intention not to renew and CMS has not provided the MA organization 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, as amended at 70 FR 4737, Jan. 28, 2005; 72 FR 68723, Dec. 5, 2007]

§ 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 by mail at least 90 calendar days before the date on which the nonrenewal is effective. The MA organization must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan, MA–PD plan, and PDP options available for obtaining qualified Medicare

services within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3) If an MA organization does not renew a contract under paragraph (a) of this section, CMS may deny an application for a new contract or a service area expansion from the MA organization for 2 years unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

(4) During the same 2-year period as specified in paragraph (a)(3) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the nonrenewing sponsor. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(b) [Reserved]

[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; 72 FR 68723, Dec. 5, 2007; 74 FR 1542, Jan. 12, 2009; 75 FR 19811, Apr. 15, 2010; 76 FR 21568, Apr. 15, 2011; 80 FR 7961, Feb. 12, 2015; 83 FR 16734, Apr. 16, 2018]

§ 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.

(3) If the organization submits a request to end the term of its contract after the deadline provided in § 422.506(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (a) through (d) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare program.

(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.

(c) *Agreement to limit new MA applications.* As a condition of the consent to a mutual termination CMS will require, as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

(d) *Prohibition against Part C program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the same 2-year period, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A ''covered person'' as used in this paragraph means one of the following:

(1) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(2) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) A member of the board of directors of the entity, if the organization is organized as a corporation.

[63 FR 35099, June 26, 1998, as amended at 75 FR 19811, Apr. 15, 2010; 76 FR 21569, Apr. 15, 2011; 80 FR 7961, Feb. 12, 2015; 83 FR 16734, Apr. 16, 2018]

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the MA organization meets any of the following:

(1) Has failed substantially to carry out the contract.

(2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(3) No longer substantially meets the applicable conditions of this part.

(4) CMS may make a determination under paragraph (a)(1), (2), or (3) of this section if the MA organization has had one or more of the following occur:

(i) Based on creditable evidence, has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid or other State or Federal health care programs, including submission of false or fraudulent data.

(ii) Substantially failed to comply with the requirements in subpart M of this part relating to grievances and appeals.

(iii) Failed to provide CMS with valid data as required under § 422.310.

(iv) Failed to implement an acceptable quality assessment and performance improvement program as required under subpart D of this part.

(v) Substantially failed to comply with the prompt payment requirements in § 422.520.

(vi) Substantially failed to comply with the service access requirements in § 422.112 or § 422.114.

(vii) Failed to comply with the requirements of § 422.208 regarding physician incentive plans.

(viii) Substantially fails to comply with the requirements in subpart V of this part.

(ix) Failed to comply with the regulatory requirements contained in this part or part 423 of this chapter or both.

(x) Failed to meet CMS performance requirements in carrying out the regulatory requirements contained in this part or part 423 of this chapter or both.

(xi) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

(xii) Has failed to report MLR data in a timely and accurate manner in accordance with § 422.2460 or that any MLR data required by this subpart is found to be materially incorrect or fraudulent.

(xiii) Fails to meet the preclusion list requirements in accordance with § 422.222 and 422.224.

(xiv) The MA organization has committed any of the acts in § 422.752(a) that support the imposition of intermediate sanctions or civil money penalties under subpart O of this part.

(xv) Following the issuance of a notice to the MA organization no later than August 1, CMS must terminate, effective December 31 of the same year, an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(xvi) Meets the criteria in § 422.514(d)(1) or (2).

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

(1) *Termination of contract by CMS.*

(i) CMS notifies the MA organization in writing at least 45 calendar days before the intended date of the termination.

(ii) The MA organization notifies its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.

(iii) The MA organization notifies the general public of the termination at

least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.

(iv) In the event that CMS issues a termination notice to an MA organization on or before August 1 with an effective date of the following December 31, the MA organization must issue notification to its Medicare enrollees at least 90 days prior to the effective date of the termination.

(2) *Immediate termination of contract by CMS.* (i) The procedures specified in paragraph (b)(1) of this section do not apply if—

(A) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization; or

(B) 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; or

(C) The contract is being terminated based on the grounds specified in paragraph (a)(4)(i) of this section.

(ii) CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If a 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.

(iii) 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.

(iv) 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) *Opportunity to develop and implement a corrective action plan*—(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the MA organization with notice specifying the MA organization's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* The MA organization will not be provided with an opportunity to develop and implement a corrective action plan prior to termination if—

(i) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization;

(ii) 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; or

(iii) The contract is being terminated based on the violation specified in (a)(4)(i) of this section.

(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; 72 FR 68723, Dec. 5, 2007; 75 FR 19811, Apr. 15, 2010; 77 FR 22168, Apr. 12, 2012; 78 FR 31307, May 23, 2013; 79 FR 29959, May 23, 2014; 81 FR 80557, Nov. 15, 2016; 83 FR 16734, Apr. 16, 2018; 88 FR 22334, Apr. 12, 2023]

§ 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.* (1) CMS may deny an application for a new contract or a service area expansion from an MA organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the contract type, product type, or service area of the previous contract.

(2) During the same 2-year period specified in paragraph (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the terminating sponsor. A ''covered person'' as used in this paragraph means one of the following:

(i) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors of the entity, if the organization is organized as a corporation.

[63 FR 35099, June 26, 1998, as amended at 67 FR 13288, Mar. 22, 2002; 76 FR 21569, Apr. 15, 2011; 80 FR 7961, Feb. 12, 2015]

§ 422.514 Enrollment requirements.

(a) *Minimum enrollment rules.* 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.* For a contract applicant that does not meet the applicable requirement of paragraph (a) of this section at application for an MA contract, CMS may waive the minimum enrollment requirement for the first 3 years of the contract. To receive a waiver, a contract applicant 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 during the first 3 years of the contract. Factors that CMS takes into consideration in making this evaluation include the extent to which—

(1) The contract applicant 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

(2) The contract applicant 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) of this section and stop-loss insurance that is adequate and acceptable to CMS; and

(3) The contract applicant 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.

(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.

(d) *Rule on dual eligible enrollment.* In any state where there is a dual eligible special needs plan or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under title XIX, CMS does not:

(1) Enter into or renew a contract under this subpart, for plan year 2024 and subsequent years, for a MA plan that—

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Projects enrollment in its bid submitted under § 422.254 that 80 percent or more enrollees of the plan's total enrollment are enrollees entitled to medical assistance under a State plan under title XIX.

(2) Renew a contract under this subpart, for plan year 2023 and subsequent years, for an MA plan that—

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under title XIX, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

(e) *Transition process and procedures.* (1) For coverage effective January 1 of the next year, and subject to the disclosure requirements described in paragraph (e)(2) of this section, an MA organization may transition enrollees in a plan specified in paragraph (d)(2) of this section into another MA plan or plans (including into a dual eligible special needs plan for enrollees who are eligible for such a plan) offered by the MA organization, or another MA organization that shares the same parent organization as the MA organization, for which the individual is eligible in accordance with §§ 422.50 through 422.53 if the MA plan or plans receiving such enrollment—

(i) Would not meet the criteria in paragraph (d)(2)(ii) of this section, as determined in the procedures described in paragraph (e)(3) of this section, with the addition of the newly enrolled individuals (unless such plan is a Specialized MA plan for Special Needs Individuals as defined in § 422.2);

(ii) Is an MA–PD plan described at § 422.2;

(iii) Has a combined Part C and Part D premium of $0.00 for individuals eligible for the premium subsidy for full

subsidy eligible individuals described in § 423.780(a) of this chapter; and

(iv) Is of the same plan type (for example, HMO or PPO) as the plan specified in paragraph (d)(2) of this section.

(2) An MA organization may transition individuals under paragraph (e)(1) of this section without requiring the individual to file the election form under § 422.66(a) if—

(i) The enrolled individual is eligible to enroll in the MA plan; and

(ii) The MA–PD plan into which individuals are transitioned describes changes to MA–PD benefits and provides information about the MA–PD plan in the Annual Notice of Change, which must be sent consistent with § 422.111(a), (d), and (e).

(3) For the purpose of approving a MA organization to transition enrollment under this paragraph (e), CMS determines whether a non-SNP MA plan would meet the criteria in paragraph (d)(2) of this section by adding the cohort of individuals identified by the MA organization for enrollment in a non-SNP MA plan to the April enrollment of such plan and calculating the resulting percentage of dual eligible enrollment.

(4) In cases where an MA organization does not transition current enrollees under paragraph (e)(1) of this section, the MA organization must send a written notice to enrollees who are not transitioned, consistent with § 422.506(a)(2).

(f) *Special considerations.* Actions taken pursuant to paragraph (d) of this section warrant special consideration to exempt affected MA organizations from the denial of an application for a new contract or service area expansion in accordance with §§ 422.502(b)(3) and (4), 422.503(b)(6) and (7), 422.506(a)(3) and (4), 422.508(c) and (d), and 422.512(e)(1) and (2).

(g) *Applicability to segments.* The rules under paragraphs (d) through (f) of this section also apply to segments of the MA plan as provided for local MA plans under § 422.262(c)(2).

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 83 FR 16734, Apr. 16, 2018; 85 FR 33908, June 2, 2020; 88 FR 22334, Apr. 12, 2023]

§ 422.516 Validation of Part C 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.

(g) *Data validation.* Each Part C sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

[63 FR 35099, June 26, 1998, as amended at 75 FR 19812, Apr. 15, 2010]

§ 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]

§ 422.530 Plan crosswalks.

(a) *General rules*—(1) *Definition of crosswalk.* A crosswalk is the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a contract between the MA organization and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions.* Except as described in paragraph (c) of this section, crosswalks are prohibited between different contracts or different plan types (for example, HMO to PPO).

(3) *Compliance with renewal/non-renewal rules.* The MA organization must comply with renewal and non-renewal rules in §§ 422.505 and 422.506 in order to complete plan crosswalks.

(4) *Eligibility.* Enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from one PBP to another PBP.

(5) *Types of MA plans.* For purposes of crosswalk policy in this section, CMS considers the following plans as different plan types:

(i) Health maintenance organizations coordinated care plans.

(ii) Provider-sponsored organizations coordinated care plans.

(iii) Regional or local preferred provider organizations coordinated care plans.

(iv) Special needs plans.

(v) Private Fee-for-service plans.

(vi) MSA plans.

(b) *Allowable crosswalk types*—(1) *All MA plans.* An MA organization may perform a crosswalk in the following circumstances:

(i) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(ii) *Consolidated renewal.* A plan in the following contract year that combines 2 or more complete current contract year plans of the same plan type but not including when a current PBP is split among more than one PBP for the following contract year. The plan ID for the following contract year must be the same as one of the current contract year plan IDs.

(iii) *Renewal with a service area expansion (SAE).* A plan in the following contract year that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(iv) *Renewal with a service area reduction (SAR).* (A) A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is

limited to the enrollees in the remaining service area.

(B) While the MA organization may not affirmatively crosswalk enrollees in the locations that will no longer be part of the service area, the MA organization may offer those affected enrollees in the reduced portion of the service area a continuation in accordance with §422.74(b)(3)(ii), provided that there are no other MA plan options in the reduced service area.

(C) If the MA organization offers another PBP in the locations that will no longer be part of the service area, current enrollees in the locations that will no longer be part of the service area must be disenrolled and the MA organization must send a non-renewal notice that includes notification of a special enrollment period under §422.62 and, for applicable enrollees, Medigap guaranteed issue rights.

(D) The MA organization may offer current enrollees in the locations that will no longer be part of the service area the option of enrolling in the other plan(s) the MA organization offers in the location that is no longer part of the service area, however, no specific plan information for the following contract year may be shared with any beneficiaries prior to the plan marketing period for the next contract year, consistent with 42 CFR 422.2263 and 423.2263.

(2) *Special needs plans (SNPs).* In addition to those described in paragraph (b)(1) of this section, SNPs may also perform the following types of crosswalks:

(i) *Chronic SNPs (C–SNPs).* (A) Renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

(B) Non-renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

(C) Non-renewing C–SNP with a grouping that is transitioning eligible enrollees into a different grouping C–SNP if the new grouping contains at least one condition that the prior C–SNP contained.

(ii) *Institutional SNP.* (A) Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(B) Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(C) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

(D) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

(E) Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

(c) *Exceptions.* In order to perform a crosswalk that is not specified in paragraph (b) of this section, an MA organization must request an exception. Crosswalk exceptions are prohibited between different plan types. CMS reviews exception requests and may permit a crosswalk exception in the following circumstances:

(1) When a non-network or partial network Private Fee-For-Service (PFFS) plan changes to either a partial network or to a full network PFFS plan, enrollees may be moved to the new plan when CMS determines it is in the interest of beneficiaries, considering whether the risks to enrollees are such that they would be better served by remaining in the plan, whether there are other suitable managed care plans available, and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. Crosswalks from a network based PFFS plan to a non-network or partial network PFFS plan will not be permitted.

(2) When MA contracts offered by two different MA organizations that share the same parent organization are consolidated such that the separate contracts are consolidated under one surviving contract, the enrollees from the consolidating contracts may be crosswalked to an MA plan under the surviving contract.

(3) When a renewing D–SNP with a multi-state service area reduces its service area or, in the case of a D–SNP

in an MA regional plan contract, nonrenews and creates state-specific local preferred provider organization plans in its place to accommodate state contracting efforts in the service area, enrollees who are no longer in the service area may be moved into one or more new or renewing D–SNPs, offered under the same parent organization (even if the D–SNPs are offered by two different MA organizations), and for which the enrollees are eligible, as CMS determines is necessary to accommodate changes to the contracts between the state and D–SNP under §422.107. For this crosswalk exception, CMS will permit enrollees to be moved between different contracts.

(4) When—

(i) A renewing D–SNP has another new or renewing D–SNP, and the two D–SNPs are offered to different populations, enrollees who are no longer eligible for their current D–SNP may be moved into the other new or renewing D–SNP offered by the same MA organization if they meet the eligibility criteria for the new or renewing D–SNP and CMS determines it is in the best interest of the enrollees to move to the new or renewing D–SNP in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception. For the crosswalk exception in this paragraph (c)(4)(i), CMS does not permit enrollees to be moved between different contracts; or

(ii) An MA organization creates a new MA contract when required by a State as described in §422.107(e), eligible enrollees may be moved from the existing D–SNP that is non-renewing, reducing its service area, or has its eligible population newly restricted by a State, to a D–SNP offered under the D–SNP-only contract, which must be of the same plan type operated by the same parent organization. For the crosswalk exception in this paragraph (c)(4)(ii), CMS permits enrollees to be moved between different contracts.

(5) Renewing C–SNP with a grouping of multiple conditions that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping.

(d) *Procedures.* (1) An MA organization must submit all crosswalks in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline announced by CMS.

(2) An MA organization must submit all crosswalk exception requests in paragraph (c)(1) of this section in writing through the crosswalk exceptions process in HPMS by the crosswalk exception request deadline announced by CMS annually. CMS verifies the requests and notifies requesting MA organizations of the approval or denial after the crosswalk exception request deadline.

[86 FR 6099, Jan. 19, 2021, as amended at 87 FR 27896, May 9, 2022]

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 of part 422 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.

(f) *Sale of beneficiaries not permitted.* (1) CMS only recognizes the sale or transfer of an organization's entire MA line of business, consisting of all MA contracts held by the MA organization with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization, which is permitted.

(2) CMS does not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries or groups of beneficiaries enrolled in a plan benefit package.

[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; 86 FR 6101, Jan. 19, 2021]

§ 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.

(4) Section 1859(f)(8) of the Act provides for, to the extent feasible, unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for Medicare and Medicaid covered items and services provided by specialized MA plans for special needs individuals described in subsection 1859(b)(6)(B)(ii) of the Act for individuals who are eligible under titles XVIII and XIX of the Act. Beginning January 1, 2021, procedures established under section 1859(f)(8) of the Act apply in place of otherwise applicable grievances and appeals procedures with respect to Medicare and Medicaid covered items and services provided by applicable integrated plans.

(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.

(5) Requirements for applicable integrated plans with respect to procedures for integrated grievances, integrated organization determinations, and integrated reconsiderations.

(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; 84 FR 15833, Apr. 16, 2019]

§ 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 (Council), and judicial review.

Applicable integrated plan means either of the following:

(1) *Before January 1, 2023.* (i) A fully integrated dual eligible special needs plan with exclusively aligned enrollment or a highly integrated dual eligible special needs plan with exclusively aligned enrollment; and

(ii) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization.

(2) *On or after January 1, 2023.* (i)(A) A fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan with exclusively aligned enrollment; and

(B) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization; or

(ii) A dual eligible special needs plan and affiliated Medicaid managed care plan where—

(A) The dual special needs plan, by State policy, has enrollment limited to those beneficiaries enrolled in a Medicaid managed care organization as described in paragraph (2)(ii)(B) of this definition;

(B) There is a capitated contract between the MA organization, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization; and

(*1*) A Medicaid agency; or

(*2*) A Medicaid managed care organization as defined in section 1903(m) of the Act that contracts with the Medicaid agency; and

(C) Through the capitated contract described in paragraph (2)(ii)(B) of this definition, Medicaid benefits including primary care and acute care, including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries, and at a minimum, one of the following: Home health services as defined in § 440.70 of this chapter, medical supplies, equipment, and appliances as described in § 440.70(b)(3) of this chapter, or nursing facility services are covered for the enrollees.

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.

Integrated appeal means any of the procedures that deal with, or result from, adverse integrated organization determinations by an applicable integrated plan 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. Integrated appeals cover procedures that would otherwise be defined and covered, for non-applicable integrated plans, as an appeal defined in § 422.561 or the procedures required for appeals in accordance with §§ 438.400 through 438.424 of this chapter. Such procedures include integrated reconsiderations.

Integrated grievance means a dispute or complaint that would be defined and covered, for grievances filed by an enrollee in non-applicable integrated plans, under § 422.564 or §§ 438.400 through 438.416 of this chapter. Integrated grievances do not include appeals procedures and QIO complaints, as described in § 422.564(b) and (c). An integrated grievance made by an enrollee in an applicable integrated plan is subject to the integrated grievance procedures in §§ 422.629 and 422.630.

Integrated organization determination means an organization determination that would otherwise be defined and covered, for a non-applicable integrated plan, as an organization determination under § 422.566, an adverse benefit determination under § 438.400(b), or an action under § 431.201 of this chapter. An integrated organization determination is made by an applicable integrated plan and is subject to the integrated organization determination procedures in §§ 422.629, 422.631, and 422.634.

Integrated reconsideration means a reconsideration that would otherwise be defined and covered, for a non-applicable integrated plan, as a reconsideration under § 422.580 and appeal under § 438.400(b) of this chapter. An integrated reconsideration is made by an applicable integrated plan and is subject to the integrated reconsideration procedures in §§ 422.629 and 422.632 through 422.634.

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 grievance or appeal. Unless otherwise stated in this subpart, the representative will have all the rights and responsibilities of an enrollee or party in filing a grievance, and 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; 75 FR 19812, Apr. 15, 2010; 82 FR 5124, Jan. 17, 2017; 84 FR 15833, Apr. 16, 2019; 84 FR 26579, June 7, 2019; 87 FR 27897, May 9, 2022]

§ 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 or, beginning January 1, 2021, § 422.630 as applicable, 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.

(4) An MA organization must employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(5) An MA organization that offers a dual eligible special needs plan has the following additional responsibilities:

(i) The dual eligible special needs plan must offer to assist an enrollee in that dual eligible special needs plan with obtaining Medicaid covered services and resolving grievances, including requesting authorization of Medicaid services, as applicable, and navigating Medicaid appeals and grievances in connection with the enrollee's own Medicaid coverage, regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2 of this chapter. If the enrollee accepts the offer of assistance, the plan must provide the assistance. Examples of such assistance include the following:

(A) Explaining to an enrollee how to make a request for Medicaid authorization of a service and how to file appeal following an adverse benefit determination, such as—

(*1*) Assisting the enrollee in identifying the enrollee's specific Medicaid managed care plan or fee-for-service point of contact;

(*2*) Providing specific instructions for contacting the appropriate agency in a fee-for-service setting or for contacting the enrollee's Medicaid managed care plan, regardless of whether the Medicaid managed care plan is affiliated with the enrollee's dual eligible special needs plan; and

(*3*) Assisting the enrollee in making contact with the enrollee's fee-for-service contact or Medicaid managed care plan.

(B) Assisting a beneficiary in filing a Medicaid grievance or a Medicaid appeal.

(C) Assisting an enrollee in obtaining documentation to support a request for authorization of Medicaid services or a Medicaid appeal.

(ii) The dual eligible special needs plan must offer to provide the assistance described in paragraph (a)(5)(i) of this section whenever it becomes aware of an enrollee's need for a Medicaid-covered service. Offering such assistance is not dependent on an enrollee's specific request.

(iii) The dual eligible special needs plan must offer to provide and actually provide assistance as required by paragraph (a)(5)(i) of this section using multiple methods.

(A) When an enrollee accepts the offer of assistance described in paragraph (a)(5)(i) of this section, the dual eligible special needs plan may coach the enrollee on how to self-advocate.

(B) The dual eligible special needs plan must also provide an enrollee reasonable assistance in completing forms and taking procedural steps related to Medicaid grievances and appeals.

(iv) The dual eligible special needs plan must, upon request from CMS, provide documentation demonstrating its compliance with this paragraph (a)(5).

(v) The obligation to provide assistance under paragraph (a)(5)(i) of this section does not create an obligation for a dual eligible special needs plan to represent an enrollee in a Medicaid appeal.

(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 or, beginning January 1, 2021, § 422.630, as applicable.

(2) The right to a timely organization determination, as provided under § 422.566 or, beginning January 1, 2021, § 422.631(c), as applicable.

(3) The right to request an expedited organization determination, as provided under §§ 422.570 or, beginning January 1, 2021, § 422.631(e), as applicable.

(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 or, beginning January 1, 2021, § 422.633, as applicable.

(ii) The right to request an expedited reconsideration, as provided under § 422.584 or, beginning January 1, 2021, § 422.633(e), as applicable.

(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 Council 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 the enrollee is not entitled to review of that issue by the MA organization.

(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.* (1) Unless this subpart provides otherwise and subject to paragraph (d)(2) of this section, 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.

(2) The following regulations in part 405 of this chapter, and any references thereto, specifically do not apply under this subpart:

(i) Section 405.950 (time frames for making a redetermination).

(ii) Section 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level).

(iii) Section 405.1016 (time frames for deciding an appeal of a QIC reconsideration, or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council).

(iv) The option to request that an appeal be escalated from the OMHA level to the Council as provided in § 405.1100(b), and time frames for the Council to decide an appeal of an ALJ's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in § 405.1100(c) and (d).

(v) Section 405.1132 (request for escalation to Federal court).

(vi) Sections 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other reference to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

(3) For the sole purpose of applying the regulations at § 405.1038(c) of this chapter, an MA organization is included in the definition of ''contractors'' as it relates to stipulated decisions.

[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; 76 FR 21569, Apr. 15, 2011; 82 FR 5110, Jan. 17, 2017; 84 FR 15834, Apr. 16, 2019; 84 FR 26579, June 7, 2019; 86 FR 6101, Jan. 19, 2021]

§ 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. For an applicable integrated plan, beginning January 1, 2021, the MA organization must comply with §§ 422.629 through 422.634 in lieu of §§ 422.566(c) and (d), 422.568, 422.570 and 422.572 with regard to the procedures for making determinations, including integrated organization determinations and integrated reconsiderations, on a standard and expedited basis.

(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) Reduction, or premature discontinuation, of a previously authorized ongoing course of treatment.

(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 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) The enrollee (including his or her representative); or

(ii) A physician (regardless of whether the physician is affiliated with the MA organization).

(d) *Who must review organization determinations.* If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

[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; 75 FR 19812, Apr. 15, 2010; 75 FR 32859, June 10, 2010; 76 FR 21569, Apr. 15, 2011; 84 FR 15834, April 16, 2019; 88 FR 22334, Apr. 12, 2023]

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Method and place for filing a request.* An enrollee must ask for a standard organization determination by making a request with the MA organization or, if applicable, to the entity responsible for making the determination (as directed by the MA organization), in accordance with the following:

(1) The request may be made orally or in writing, except as provided in paragraph (a)(2) of this section.

(2) Requests for payment must be made in writing (unless the MA organization or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(b) *Timeframes*—(1) *Requests for service or item.* Except as provided in paragraph (b)(1)(i) of this section, when a party has made a request for a service or an item, 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.

(i) *Extensions; requests for service or item.* The MA organization may extend the timeframe by up to 14 calendar days if—

(A) The enrollee requests the extension;

(B) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(C) The extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest.

(ii) *Notice of extension.* 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.

(2) *Requests for a Part B drug.* An MA organization must notify the enrollee (and the prescribing physician or other prescriber 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. This 72-hour period may not be extended under the provisions in paragraph (b)(1)(i) of this section.

(c) *Timeframe for requests for payment.* The MA organization must process requests for payment according to the ''prompt payment'' provisions set forth in § 422.520.

(d) *Written notice for MA organization denials.* The MA organization must give the enrollee a written notice if—

(1) An MA organization decides to deny a service or an item, Part B drug, or payment in whole or in part, or reduce or prematurely discontinue the level of care for a previously authorized ongoing course of treatment.

(2) An enrollee requests an MA organization to provide an explanation of a practitioner's denial of an item, service or Part B drug, in whole or in part.

(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, item, and Part B drug 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.

(g) *Dismissing a request.* The MA organization dismisses an organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an organization determination under § 422.566(c).

(2) The MA organization determines the party failed to make out a valid request for an organization determination that substantially complies with paragraph (a) of this section.

(3) An enrollee or the enrollee's representative files a request for an organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the organization determination.

(4) A party filing the organization determination request submits a timely request for withdrawal of their request for an organization determination with the MA organization.

(h) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the organization determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(i) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for an organization determination within 6 months from the date of the notice of dismissal.

(j) *Effect of dismissal.* The dismissal of a request for an organization determination is binding unless it is modified or reversed by the MA organization upon reconsideration or vacated under paragraph (i) of this section.

(k) *Withdrawing a request.* A party that requests an organization determination may withdraw its request at any time before the decision is issued by filing a request with the MA organization.

[65 FR 40329, June 29, 2000, as amended at 70 FR 4739, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 75 FR 19812, Apr. 15, 2010; 75 FR 32859, June 10, 2010; 80 FR 7961, Feb. 12, 2015; 84 FR 23880, May 23, 2019; 86 FR 6101, Jan. 19, 2021]

§ 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 72-hour or 14-day timeframe, as applicable, established in § 422.568 for a standard determination. The timeframe begins when 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.

(g) *Dismissing a request.* The MA organization dismisses an expedited organization request in accordance with § 422.568.

[63 FR 35107, June 26, 1998, as amended at 65 FR 40329, June 29, 2000; 70 FR 4739, Jan. 28, 2005; 84 FR 23880, May 23, 2019; 86 FR 6101, Jan. 19, 2021]

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframes*—(1) *Requests for service or item.* 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.

(2) *Requests for a Part B drug.* An MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician or prescriber involved, as appropriate) of its decision as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. This 24-hour period may not be extended under the provisions in paragraph (b) of this section.

(b) *Extensions; requests for service or item.* (1) When timeframe may be extended. The MA organization may extend the 72-hour deadline for expedited organization determinations for requests for services or items by up to 14 calendar days if—

(i) The enrollee requests the extension;

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent, or other nonroutine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* 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; 80 FR 7961, Feb. 12, 2015; 84 FR 23881, May 23, 2019]

§ 422.574 Parties to the organization determination.

The parties to the organization determination are—

(a) The enrollee (including his or her 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.

[63 FR 35107, June 26, 1998, as amended at 75 FR 19812, Apr. 15, 2010]

§ 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. A physician who is providing treatment to an enrollee may, upon providing notice to the enrollee, request a standard reconsideration of a pre-service request for reconsideration on the enrollee's behalf as described in § 422.582. An enrollee or physician (acting on behalf of an enrollee) may request an expedited reconsideration as described in § 422.584.

[74 FR 1542, Jan. 12, 2009]

§ 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 or, upon providing notice to the enrollee, a physician who is treating an enrollee and acting on the enrollee's behalf, 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 request for reconsideration must be filed 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 or physician acting on behalf of an enrollee 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 or a physician acting on behalf of an enrollee 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 or physician acting on behalf of an enrollee who files a request for reconsideration may withdraw it by filing a request for withdrawal at one of the places listed in paragraph (a) of this section.

(f) *Dismissing a request.* The MA organization dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578.

(2) The MA organization determines the party failed to make a valid request for a reconsideration that substantially complies with paragraph (a) of this section.

(3) The party fails to file the reconsideration request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(5) A party filing the reconsideration request submits a timely request for withdrawal of the request for a reconsideration with the MA organization.

(g) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(h) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(i) *Effect of dismissal.* The MA organization's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the decision is vacated under paragraph (h) of this section.

[74 FR 1542, Jan. 12, 2009, as amended at 86 FR 6101, Jan. 19, 2021]

§ 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 calendar day or 7 calendar day, as applicable, timeframe established in §422.590(a) and (c). The timeframe 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.

(g) *Dismissing a request.* The MA organization dismisses an expedited reconsideration request in accordance with §422.582(f) through (i).

[63 FR 35107, June 26, 1998, as amended at 65 FR 40330, June 29, 2000; 70 FR 4739, Jan. 28, 2005; 84 FR 23881, May 23, 2019; 86 FR 6101, Jan. 19, 2021]

§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: Requests for service or item.* (1) Except as provided in paragraph (f) of this section, 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.

(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: Requests 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)(2)) 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) *Standard reconsideration: Requests for a Part B drug.* (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)(3)) 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 reconsideration. This 7 calendar-day period may not be extended under the provisions in paragraph (f) of this section.

(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 with CMS no later than 7 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 the information to the independent entity.

(d) *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), (b), or (c) 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), (b)(2), and (c)(2) of this section.

(e) *Expedited reconsideration*—(1) *Timeframe for services or items.* Except as provided in paragraph (f) 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) *Timeframe for Part B drugs.* An MA organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician or other prescriber 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. This 72-hour period may not be extended under the provisions in paragraph (f) of this section.

(3) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of a completely favorable expedited reconsideration orally, 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.

(f) *Extensions; requests for service or item.* (1) As described in paragraphs (f)(1)(i) through (iii) of this section, the MA organization may extend the standard or expedited reconsideration deadline for services by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent or other nonroutine circumstances and is in the enrollee's interest.

(2) 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.

(g) *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 (e)(1) or (2) of this section, as applicable, 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 (e)(1) or (2) of this section.

(h) *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.

(i) *Requests for review of a dismissal by the independent entity.* If the MA organization dismisses a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g), the enrollee or other proper party under § 422.578 has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the MA organization's dismissal notice.

[84 FR 23881, May 23, 2019, as amended at 86 FR 6102, Jan. 19, 2021; 88 FR 22334, Apr. 12, 2023]

§ 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. In accordance with § 422.590(i), the independent entity is responsible for reviewing MA organization dismissals of reconsideration requests.

(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.

(d) The independent entity dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578.

(2) The independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with § 422.582(a) or (b).

(3) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(4) The party filing the reconsideration request submits with the independent review entity a timely request for withdrawal of the request for reconsideration.

(e) The independent entity mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the independent entity vacate the dismissal action.

(3) The right to a review of the dismissal under §§ 422.600 and 422.602.

(f) If good cause is established, the independent entity may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(g) The independent entity's dismissal is binding and not subject to further review unless a party meets the requirements in § 422.600 and files a proper and timely request under § 422.602 or the dismissal is vacated under paragraph (f) of this section.

(h) The party or physician acting on behalf of an enrollee who files a request for reconsideration may withdraw the request by filing a request for withdrawal with the independent entity.

(i) If the independent entity determines that the MA organization's dismissal was in error, the independent entity vacates the dismissal and remands the case to the plan for reconsideration consistent with § 422.590. The independent entity's decision regarding an MA organization's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

[63 FR 35107, June 26, 1998, as amended at 86 FR 6102, Jan. 19, 2021]

§ 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 meets the requirements of § 422.600;

(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; 82 FR 5125, Jan. 17, 2017]

§ 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. For purposes of calculating the amount remaining in controversy under this section, references to coinsurance in § 405.1006(d) of this chapter should be read to include coinsurance and copayment amounts.

(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; 86 FR 6102, Jan. 19, 2021]

§ 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.* (1) Except when an ALJ or attorney adjudicator extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 calendar days of receipt 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 of this chapter.

(2) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary.

(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; 82 FR 5125, Jan. 17, 2017]

§ 422.608 Medicare Appeals Council (Council) review.

Any party to the ALJ's or attorney adjudicator's decision or dismissal, including the MA organization, who is dissatisfied with the decision or dismissal, may request that the Council review the decision or dismissal. The regulations under part 405 of this chapter regarding Council review apply to matters addressed by this subpart to the extent that they are appropriate, except as provided in § 422.562(d)(2).

[82 FR 5125, Jan. 17, 2017]

§ 422.612 Judicial review.

(a) *Review of ALJ's or attorney adjudicator's decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of an ALJ's or attorney adjudicator's decision if—

(1) The Council 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 Council decision.* Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the Council 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; 82 FR 5125, Jan. 17, 2017]

§ 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 attorney adjudicator or the Council 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; 82 FR 5125, Jan. 17, 2017]

§ 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(f)).

(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.

(3) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 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.

(3) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, 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 Part B drug under dispute within 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 determination is reversed in whole or in part by the ALJ or attorney adjudicator, 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 Council.* If the MA organization requests Council 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 Council 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; 80 FR 7962, Feb. 12, 2015; 82 FR 5125, Jan. 17, 2017; 84 FR 23882, May 23, 2019]

§ 422.619 How an MA organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the MA organization*—(1) *Requests for service or item.* 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 or item 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(f)).

(2) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the Part B drug 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.

(b) *Reversals by the independent outside entity*—(1) *Requests for service or item.* 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.

(2) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, 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 Part B drug 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 MA organization must inform the 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 attorney adjudicator, 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) *Reversals of decisions related to Part B drugs.* If the independent outside entity's determination is reversed in whole or in part by an ALJ/attorney adjudicator or at a higher level of appeal, the MA organization must authorize or provide the Part B drug 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 MA organization must inform the outside entity that the organization has effectuated the decision.

(3) *Effectuation exception when the MA organization files an appeal with the Council.* If the MA organization requests Council 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 Council 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; 80 FR 7962, Feb. 12, 2015; 82 FR 5125, Jan. 17, 2017; 84 FR 23882, May 23, 2019]

§ 422.620 Notifying enrollees of hospital discharge appeal rights.

(a) *Applicability and scope.* (1) For purposes of §§ 422.620 and 422.622, the term hospital is defined as any facility providing care at the inpatient hospital level, whether that care is short term or long term, acute or non acute, paid through a prospective payment system or other reimbursement basis, limited to specialty care or providing a broader spectrum of services. This definition also includes critical access hospitals.

(2) For purposes of §§ 422.620 and 422.622, a discharge is a formal release of an enrollee from an inpatient hospital.

(b) *Advance written notice of hospital discharge rights.* For all Medicare Advantage enrollees, hospitals must deliver valid, written notice of an enrollee's rights as a hospital inpatient including discharge appeal rights. The hospital must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* The hospital must provide the notice at or near admission, but no later than 2 calendar days following the enrollee's admission to the hospital.

(2) *Content of the notice.* The notice of rights must include the following information:

(i) The enrollee's rights as a hospital inpatient, including the right to benefits for inpatient services and for post hospital services in accordance with 1866(a)(1)(M) of the Act.

(ii) The enrollee's right to request an immediate review, including a description of the process under § 422.622 and the availability of other appeals processes if the enrollee fails to meet the deadline for an immediate review.

(iii) The circumstances under which an enrollee will or will not be liable for charges for continued stay in the hospital in accordance with 1866(a)(1)(M) of the Act.

(iv) The enrollee's right to receive additional information in accordance with section § 422.622(e).

(v) Any other information required by CMS.

(3) *When delivery of notice is valid.* Delivery of the written notice of rights described in this section is valid if—

(i) The enrollee (or the enrollee's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents, except as provided in paragraph (b)(4) of this section; and

(ii) 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.

(4) *If an enrollee refuses to sign the notice.* The hospital may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(c) *Follow up notification.* (1) The hospital must present a copy of the signed notice described in paragraph (b)(2) of this section to the enrollee (or enrollee's representative) prior to discharge. The notice should be given as far in advance of discharge as possible, but not more than 2 calendar days before discharge.

(2) Follow up notification is not required if the notice required under 422.620(b) is delivered within 2 calendar days of discharge.

(d) *Physician concurrence required.* Before discharging an enrollee from the inpatient hospital level of care, the MA organization must obtain concurrence from the physician who is responsible for the enrollee's inpatient care.

[71 FR 68723, Nov. 27, 2006]

§ 422.622 Requesting immediate QIO review of the decision to discharge from the inpatient hospital.

(a) *Enrollee's right to an immediate QIO review.* An enrollee has a right to request an immediate review by the QIO when an MA organization or hospital (acting directly or through its utilization committee), with physician concurrence determines that inpatient care is no longer necessary.

(b) *Requesting an immediate QIO review.* (1) An enrollee who wishes to exercise the right to an immediate review must submit a request to the QIO that has an agreement with the hospital as specified in § 476.78 of this chapter. The request must be made no later than the day of discharge and may be in writing or by telephone.

(2) The enrollee, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The enrollee may, but is not required to, submit written evidence to be considered by a QIO in making its decision.

(4) An enrollee who makes a timely request for an immediate QIO review in accordance with paragraph (b)(1) of this section is subject to the financial liability protections under paragraph (f) of this section, as applicable.

(5) When an enrollee does not request an immediate QIO review in accordance with paragraph (b) of this section, he or she may request expedited reconsideration by the MA organization as described in § 422.584, but the financial liability rules of paragraph (f) of this section do not apply.

(c) *Burden of proof.* When an enrollee (or his or her representative, if applicable) requests an immediate review by a QIO, the burden of proof rests with the MA organization to demonstrate that discharge is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies. Consistent with paragraph (e)(2) of this section, the MA organization should supply any and all information that a QIO requires to sustain the organization's discharge determination.

(d) *Procedures the QIO must follow.* (1) When the QIO receives the enrollee's request for an immediate review under paragraph (b), the QIO must notify the MA organization and the hospital that the enrollee has filed a request for an immediate review.

(2) The QIO determines whether the hospital delivered valid notice consistent with § 422.620(b)(3).

(3) The QIO examines the medical and other records that pertain to the services in dispute.

(4) The QIO must solicit the views of the enrollee (or his or her representative) who requested the immediate QIO review.

(5) The QIO must provide an opportunity for the MA organization to explain why the discharge is appropriate.

(6) When the enrollee requests an immediate QIO review in accordance with paragraph (b)(1) of this section, the QIO must make a determination and notify the enrollee, the hospital, the MA organization, and the physician of its determination within one calendar day after it receives all requested pertinent information.

(7) If the QIO does not receive the information needed to sustain an MA organization's decision to discharge, it may make its determination based on the evidence at hand, or it may defer a decision until it receives the necessary information. If this delay results in extended Medicare coverage of an individual's hospital services, the MA organization may be held financially liable for these services, as determined by the QIO.

(8) When the QIO issues its determination, the QIO must notify the enrollee, the MA organization, the physician, and hospital of its decision by telephone, followed by a written notice that must include the following information:

(i) The basis for the determination.

(ii) A detailed rationale for the determination.

(iii) An explanation of the Medicare payment consequences of the determination and the date an enrollee becomes fully liable for the services.

(iv) Information about the enrollee's right to a reconsideration of the QIO's determination as set forth in § 422.626(f), including how to request a reconsideration and the time period for doing so.

(e) *Responsibilities of the MA organization and hospital.* (1) When the QIO notifies an MA organization that an enrollee has requested an immediate QIO review, the MA organization must, directly or by delegation, deliver a detailed notice to the enrollee as soon as possible, but no later than noon of the day after the QIO's notification. The detailed notice must include the following information:

(i) A detailed explanation of 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 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 discharge determination was based.

(iv) Facts specific to the enrollee and relevant to the coverage determination 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 notification by the QIO of a request for an immediate review, the MA organization must supply any and all information, including a copy of the notices sent to the enrollee, as specified in § 422.620(b) and (c) and paragraph (e)(1) of this section, that the QIO needs to decide on the determination. The MA organization must supply this information as soon as possible, but no later than noon of the day after the QIO notifies the MA organization that a request for an expedited determination has been received from the enrollee. The MA organization must make the information available by phone (with a written record made of any information not transmitted initially in writing) and/or in writing, as determined by the QIO.

(3) In response to a request from the MA organization, the hospital must supply all information that the QIO needs to make its determination, including a copy of the notices required as specified in § 422.620(b) and (c) and paragraph (e)(1) of this section. The hospital must furnish this information as soon as possible, but no later than by close of business of the day the MA organization notifies the hospital of the request for information. At the discretion of the QIO, the hospital must make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(4) Upon an enrollee's request, the MA organization must provide the enrollee a copy of, or access to, any documentation sent to the QIO by the MA organization, including written records of any information provided by telephone. The MA organization may charge the enrollee a reasonable amount to cover the costs of duplicating the documentation 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.

(f) *Coverage during QIO expedited review.* (1) An MA organization is financially responsible for coverage of services as provided in this paragraph, regardless of whether it has delegated responsibility for authorizing coverage or discharge determinations to its providers.

(2) When the MA organization determines that hospital services are not, or are no longer, covered,

(i) 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 MA organization continues to be financially responsible for the costs of the hospital stay when an appeal is filed under paragraph (a)(1) of this section until noon of the day after the QIO notifies the enrollee of its review determination, except as provided in paragraph (b)(5) of this section. 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 non-coverage determination made by the MA organization.

(3) If the QIO determines that the enrollee still requires inpatient hospital care, the hospital must provide the enrollee with a notice consistent with § 422.620(c) of this subpart when the hospital or MA organization once again determines that the enrollee no longer requires inpatient hospital care.

(4) If the hospital determines that inpatient hospital services are no longer necessary, the hospital may not charge the enrollee for inpatient services received before noon of the day after the QIO notifies the enrollee of its review determination.

(g) *Effect of an expedited QIO determination.* The QIO determination is binding upon the enrollee, physician, hospital, and MA organization except in the following circumstances:

(1) *Right to request a reconsideration.* If the enrollee is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 422.626(g).

(2) *Right to pursue the standard appeal process.* If the enrollee is no longer an inpatient in the hospital and is dissatisfied with this determination, the enrollee may appeal to OMHA for an ALJ hearing, the Council, or a Federal court, as provided for under this subpart.

[71 FR 68723, Nov. 27, 2006, as amended at 75 FR 19812, Apr. 15, 2010; 76 FR 21569, Apr. 15, 2011; 82 FR 5125, Jan. 17, 2017]

§ 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 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.

[68 FR 16667, Apr. 4, 2003, as amended at 75 FR 19812, Apr. 15, 2010]

§ 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.

(f) *Responsibilities of the provider.* If an IRE reverses an MA organization's termination decision, the provider must provide the enrollee with a new notice consistent with § 422.624(b) of this subpart.

(g) *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

appeal the IRE's reconsidered determination to OMHA for an ALJ hearing, the Council, 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.

[68 FR 16667, Apr. 4, 2003, as amended at 75 FR 19812, Apr. 15, 2010; 76 FR 21569, Apr. 15, 2011; 82 FR 5125, Jan. 17, 2017]

Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans

Source: 84 FR 15835, Apr. 16, 2019, unless otherwise noted.

§ 422.629 General requirements for applicable integrated plans.

(a) *Scope.* The provisions in this section and in §§ 422.630 through 422.634 set forth requirements for unified appeals and grievance processes with which applicable integrated plans must comply. Beginning January 1, 2021, these provisions apply to an applicable integrated plan in lieu of §§ 422.564, 422.566(c) and (d), and 422.568 through 422.590, and 422.618(a) and §§ 438.404 through 438.424 of this chapter; provisions governing Part B drugs in §§ 422.568(b)(2), 422.570(d)(2), 422.572(a)(2), 422.584(d)(1), 422.590(c), and 422.590(e)(2) apply to an applicable integrated plan.

(b) *General process.* An applicable integrated plan must create integrated processes for enrollees for integrated grievances, integrated organization determinations, and integrated reconsiderations.

(c) *State flexibilities.* A State may, at its discretion, implement standards for timeframes or notice requirements that are more protective for the enrollee than required by this section and §§ 422.630 through 422.634. The contract under § 422.107 must include any standards that differ from the standards set forth in this section.

(d) *Evidence.* The applicable integrated plan must do the following:

(1) Provide the enrollee—

(i) A reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, and integrated reconsiderations; and

(ii) Information on how evidence and testimony should be presented to the plan.

(2) Inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

(e) *Assistance.* In addition to the requirements in § 422.562(a)(5), the applicable integrated plan must provide an enrollee reasonable assistance in completing forms and taking other procedural steps related to integrated grievances and integrated appeals.

(f) *Applicable requirements.* The requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626 apply to an applicable integrated plan unless otherwise provided in this section or in §§ 422.630 through 422.634.

(g) *Acknowledgement.* The applicable integrated plan must send to the enrollee written acknowledgement of integrated grievances and integrated reconsiderations upon receiving the request.

(h) *Recordkeeping.* (1) The applicable integrated plan must maintain records of integrated grievances and integrated appeals. Each applicable integrated plan that is a Medicaid managed care organization must review the Medicaid-related information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(2) The record of each integrated grievance or integrated appeal must contain, at a minimum:

(i) A general description of the reason for the integrated appeal or integrated grievance.

(ii) The date of receipt.

(iii) The date of each review or, if applicable, review meeting.

(iv) Resolution at each level of the integrated appeal or integrated grievance, if applicable.

(v) Date of resolution at each level, if applicable.

(vi) Name of the enrollee for whom the integrated appeal or integrated grievance was filed.

(vii) Date the applicable integrated plan notified the enrollee of the resolution.

(3) The record of each integrated grievance or integrated appeal must be accurately maintained in a manner accessible to the State and available upon request to CMS.

(i) *Prohibition on punitive action.* Each applicable integrated plan must ensure that no punitive action is taken against a provider that requests an integrated organization determination or integrated reconsideration, or supports an enrollee's request for these actions.

(j) *Information to providers and subcontractors.* The applicable integrated plan must provide information about the integrated grievance and integrated appeal system to all providers and subcontractors at the time they enter into a contract including, at minimum, information on integrated grievance, integrated reconsideration, and fair hearing procedures and timeframes as applicable. Such information must include the following:

(1) The right to file an integrated grievance and integrated reconsideration.

(2) The requirements and timeframes for filing an integrated grievance or integrated reconsideration.

(3) The availability of assistance in the filing process.

(k) *Review decision-making requirements*—(1) *General rules.* Individuals making decisions on integrated appeals and grievances must take into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse integrated organization determination.

(2) *Integrated grievances.* Individuals making decisions on integrated grievances must be individuals who—

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual; and

(ii) If deciding any of the following, have the appropriate clinical expertise in treating the enrollee's condition or disease:

(A) A grievance regarding denial of expedited resolution of an appeal.

(B) A grievance that involves clinical issues.

(3) *Integrated organization determinations.* If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(4) *Integrated reconsideration determinations.* Individuals making an integrated reconsideration determination must be individuals who—

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual; and

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise in treating the enrollee's condition or disease, and knowledge of

Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated reconsideration determination.

(l) *Parties.* (1) The following individuals or entities can request an integrated grievance, integrated organization determination, and integrated reconsideration, and are parties to the case:

(i) The enrollee.

(ii) The enrollee's representative, including any person authorized under State law.

(2) When the term ''enrollee'' is used throughout §§ 422.629 through 422.634, it includes providers that file a request and authorized representatives consistent with this paragraph, unless otherwise specified.

(3) A provider who is providing treatment to the enrollee may, upon providing notice to the enrollee, request a standard or expedited pre-service integrated reconsideration on behalf of an enrollee.

(4) The following individuals or entities may request an integrated reconsideration and are parties to the case:

(i) An assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service).

(ii) Any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding.

[84 FR 15835, Apr. 16, 2019, as amended at 84 FR 23883, May 23, 2019; 86 FR 6102, Jan. 19, 2021; 87 FR 27897, May 9, 2022; 88 FR 22335, Apr. 12, 2023]

§ 422.630 Integrated grievances.

(a) *General rule.* In lieu of complying with § 422.564, and the grievance requirements of §§ 438.402, 438.406, 438.408, 438.414, and 438.416 of this chapter, each applicable integrated plan must comply with this section. Each applicable integrated plan must provide meaningful procedures for timely hearing and resolving integrated grievances between enrollees and the applicable integrated plan or any other entity or individual through which the applicable integrated plan provides covered items and services.

(b) *Timing.* An enrollee may file an integrated grievance at any time with the applicable integrated plan.

(c) *Filing.* An enrollee may file an integrated grievance orally or in writing with the applicable integrated plan, or with the State for an integrated grievance related to a Medicaid benefit, if the State has a process for accepting Medicaid grievances.

(d) *Expedited grievances.* An applicable integrated plan must respond to an enrollee's grievance within 24 hours if the complaint involves the applicable integrated plan's—

(1) Decision to invoke an extension relating to an integrated organization determination or integrated reconsideration; or

(2) Refusal to grant an enrollee's request for an expedited integrated organization determination under § 422.631 or expedited integrated reconsideration under § 422.633.

(e) *Resolution and notice.* (1) The applicable integrated plan must resolve standard integrated grievances as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days from the date it receives the integrated grievance.

(i) All integrated grievances submitted in writing must be responded to in writing.

(ii) Integrated grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All integrated grievances related to quality of care, regardless of how the integrated 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 with regard to Medicare covered services. For any complaint submitted to a QIO, the applicable integrated plan must cooperate with the QIO in resolving the complaint.

(2) The timeframe for resolving the integrated grievance may be extended by 14 calendar days if the enrollee requests an extension or if the applicable integrated plan justifies the need for additional information and documents how the delay is in the interest of the

enrollee. When the applicable integrated plan extends the timeframe, it must—

(i) Make reasonable efforts to promptly notify the enrollee orally of the reasons for the delay; and

(ii) Send written notice to the enrollee of the reasons for the delay immediately, but no later than within 2 calendar days of making the decision to extend the timeframe to resolve the integrated grievance. This notice must explain the right to file an integrated grievance if the enrollee disagrees with the decision to delay.

§ 422.631 Integrated organization determinations.

(a) *General rule.* An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits. Timeframes and notice requirements for integrated organization determinations for Part B drugs are governed by the provisions for Part B drugs in §§ 422.568(b)(2), 422.570(d)(2), and 422.572(a)(2).

(b) *Requests.* The enrollee, or a provider on behalf of an enrollee, may request an integrated organization determination orally or in writing, except for requests for payment, which must be in writing (unless the applicable integrated plan or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(c) *Expedited integrated organization determinations.* (1) An enrollee, or a provider on behalf of an enrollee, may request an expedited integrated organization determination.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must complete an expedited integrated organization determination when the applicable integrated plan determines (based on a request from the enrollee or on its own) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(d) *Timeframes and notice*—(1) *Integrated organization determination notice.* (i) The applicable integrated plan must send an enrollee a written notice of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in this section.

(ii) For an integrated organization determination not reached within the timeframes specified in this section (which constitutes a denial and is thus an adverse decision), the applicable integrated plan must send a notice on the date that the timeframes expire. Such notice must describe all applicable Medicare and Medicaid appeal rights.

(iii) Integrated organization determination notices must be written in plain language, be available in a language and format that is accessible to the enrollee, and explain the following:

(A) The applicable integrated plan's determination.

(B) The date the determination was made.

(C) The date the determination will take effect.

(D) The reasons for the determination.

(E) The enrollee's right to file an integrated reconsideration and the ability for someone else to file an appeal on the enrollee's behalf.

(F) Procedures for exercising enrollee's rights to an integrated reconsideration.

(G) Circumstances under which expedited resolution is available and how to request it.

(H) If applicable, the enrollee's rights to have benefits continue pending the resolution of the integrated appeal process.

(2) *Timing of notice*—(i) *Standard integrated organization determinations.* (A) The applicable integrated plan must send a notice of its integrated organization determination at least 10 days

before the date of action (that is, before the date on which a termination, suspension, or reduction becomes effective), in cases where a previously approved service is being reduced, suspended, or terminated, except in circumstances where an exception is permitted under §§431.213 and 431.214 of this chapter.

(B) For other integrated organization determinations that are not expedited integrated organization determinations, the applicable integrated plan must send a notice of its integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from when it receives the request for the integrated organization determination.

(ii) *Extensions.* The applicable integrated plan may extend the timeframe for a standard or expedited integrated organization determination by up to 14 calendar days if—

(A) The enrollee or provider requests the extension; or

(B) The applicable integrated plan can show that—

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(iii) *Notices in cases of extension.* (A) When the applicable integrated plan extends the timeframe, it must notify the enrollee in writing of the reasons for the delay as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension, and inform the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision to grant an extension.

(B) If the applicable integrated plan extends the timeframe for making its integrated organization determination, it must send the notice of its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(iv) *Expedited integrated organization determinations.* (A) The applicable integrated plan must provide notice of its expedited integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(B) If the applicable integrated plan denies the request for an expedited integrated organization determination, it must:

(*1*) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in this paragraph for a standard integrated organization determination. The 14-day period begins with the day the applicable integrated plan receives the request for expedited integrated organization determination.

(*2*) Give the enrollee prompt oral notice of the denial and transfer and subsequently deliver, within 3 calendar days, a written letter that—

(*i*) Explains that the applicable integrated plan will process the request using the 14-day timeframe for standard integrated organization determinations;

(*ii*) Informs the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision not to expedite;

(*iii*) Informs the enrollee of the right to resubmit a request for an expedited integrated organization determination with any physician's support; and

(*iv*) Provides instructions about the integrated grievance process and its timeframes.

(C) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting

the timeframe and notice requirements of this section.

(3) *Timeframe for requests for payment.* The applicable integrated plan must process requests for payment according to the ''prompt payment'' provisions set forth in § 422.520.

(e) *Dismissing a request.* The applicable integrated plan dismisses a standard or expedited integrated organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an integrated organization determination under § 422.629(*l*).

(2) The applicable integrated plan determines the party failed to make out a valid request for an integrated organization determination that substantially complies with paragraph (b) of this section.

(3) An enrollee or the enrollee's representative files a request for an integrated organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated organization determination.

(4) A party filing the integrated organization determination request submits a timely request for withdrawal of their request for an integrated organization determination with the applicable integrated plan.

(f) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated organization determination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(g) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for an integrated organization determination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for an integrated organization determination is binding unless it is modified or reversed by the applicable integrated plan or vacated under paragraph (g) of this section.

(i) *Withdrawing a request.* A party that requests an integrated organization determination may withdraw its request at any time before the decision is issued by filing a request with the applicable integrated plan.

[84 FR 15835, Apr. 16, 2019, as amended at 84 FR 23883, May 23, 2019; 86 FR 6102, Jan. 19, 2021; 87 FR 27897, May 9, 2022]

§ 422.632 Continuation of benefits while the applicable integrated plan reconsideration is pending.

(a) *Definition.* As used in this section, timely files means files for continuation of benefits on or before the later of the following:

(1) Within 10 calendar days of the applicable integrated plan sending the notice of adverse integrated organization determination.

(2) The intended effective date of the applicable integrated plan's proposed adverse integrated organization determination.

(b) *Continuation of benefits.* The applicable integrated plan must continue the enrollee's benefits under Parts A and B of title XVIII and title XIX if all of the following occur:

(1) The enrollee files the request for an integrated appeal timely in accordance with § 422.633(d);

(2) The integrated appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the applicable integrated plan continues or reinstates the enrollee's benefits, as described in paragraph (b) of this section, while the integrated reconsideration is pending, the benefits must be continued until—

(1) The enrollee withdraws the request for an integrated reconsideration;

(2) The applicable integrated plan issues an integrated reconsideration that is unfavorable to the enrollee related to the benefit that has been continued;

(3) For an appeal involving Medicaid benefits—

(i) The enrollee fails to file a request for a State fair hearing and continuation of benefits, within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration;

(ii) The enrollee withdraws the appeal or request for a State fair hearing; or

(iii) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Recovery of costs.* In the event the appeal or State fair hearing is adverse to the enrollee—

(1) The applicable integrated plan or State agency may not pursue recovery for costs of services furnished by the applicable integrated plan pending the integrated reconsideration, to the extent that the services were furnished solely under of the requirements of this section.

(2) If, after the integrated reconsideration decision is final, an enrollee requests that Medicaid services continue through a State fair hearing, state rules on recovery of costs, in accordance with the requirements of § 438.420(d) of this chapter, apply for costs incurred for services furnished pending appeal subsequent to the date of the integrated reconsideration decision.

[84 FR 15835, Apr. 16, 2019, as amended at 86 FR 6103, Jan. 19, 2021]

§ 422.633 Integrated reconsiderations.

(a) *General rule.* An applicable integrated plan may only have one level of integrated reconsideration for an enrollee.

(b) *External medical reviews.* If a State has established an external medical review process, the requirements of § 438.402(c)(1)(i)(B) of this chapter apply to each applicable integrated plan that is a Medicaid managed care organization, as defined in section 1903 of the Act.

(c) *Case file.* Upon request of the enrollee or his or her representative, the applicable integrated plan must provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the applicable integrated plan (or at the direction of the applicable integrated plan) in connection with the appeal of the integrated organization determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for the integrated reconsideration, or subsequent appeal, as specified in this section.

(d) *Timing.* (1) *Timeframe for filing*—An enrollee has 60 calendar days from the date on the adverse organization determination notice to file a request for an integrated reconsideration with the applicable integrated plan.

(2) *Oral inquires*—Oral inquires seeking to appeal an adverse integrated organization determination must be treated as a request for an integrated reconsideration (to establish the earliest possible filing date for the appeal).

(3) *Extending the time for filing a request*—(i) *General rule.* If a party or physician acting on behalf of an enrollee shows good cause, the applicable integrated plan may extend the timeframe for filing a request for an integrated reconsideration.

(ii) *How to request an extension of timeframe.* If the 60-day period in which to file a request for an integrated reconsideration has expired, a party to the integrated organization determination or a physician acting on behalf of an enrollee may file a request for integrated reconsideration with the applicable integrated plan. The request for integrated reconsideration and to extend the timeframe must—

(A) Be in writing; and

(B) State why the request for integrated reconsideration was not filed on time.

(e) *Expedited integrated reconsiderations.* (1) Applicable integrated plans

must accept requests to expedite integrated reconsiderations from either of the following:

(i) An enrollee.

(ii) A provider making the request on behalf of an enrollee, when the request is not a request for expedited payment.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must grant the request to expedite the integrated reconsideration when it determines (for a request from the enrollee), or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request), that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(4) If an applicable integrated plan denies an enrollee's request for an expedited integrated reconsideration, it must automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in paragraph (f)(1) of this section for a standard integrated reconsideration. The 30-day period begins with the day the applicable integrated plan receives the request for expedited integrated reconsideration. The applicable integrated plan must give the enrollee prompt oral notice of the decision, and give the enrollee written notice within 2 calendar days. The written notice must do all of the following:

(i) Include the reason for the denial.

(ii) Inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision not to expedite, including timeframes and procedures for filing a grievance.

(iii) Inform the enrollee of the right to resubmit a request for an expedited determination with any physician's support.

(5) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

(f) *Resolution and notification.* The applicable integrated plan must make integrated reconsidered determinations as expeditiously as the enrollee's health condition requires but no later than the timeframes established in this section. Integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2).

(1) *Standard integrated reconsiderations.* The applicable integrated plan must resolve integrated reconsiderations as expeditiously as the enrollee's health condition requires but no later than 30 calendar days from the date of receipt of the request for the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section.

(2) *Expedited integrated reconsiderations.* The applicable integrated plan must resolve expedited integrated reconsiderations as expeditiously as the enrollee's health condition requires but no later than within 72 hours of receipt of the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section. In addition to the written notice required under paragraph (f)(4) of this section, the applicable integrated plan must make reasonable efforts to provide prompt oral notice of the expedited resolution to the enrollee.

(3) *Extensions.* (i) The applicable integrated plan may extend the timeframe for resolving any integrated reconsideration other than those concerning Part B drugs by 14 calendar days if—

(A) The enrollee requests the extension; or

(B) The applicable integrated plan can show that—

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(ii) If the applicable integrated plan extends the timeframe for resolving the integrated reconsideration, it must make reasonable efforts to give the enrollee prompt oral notice of the delay, and give the enrollee written notice within 2 calendar days of making the decision to extend the timeframe to resolve the integrated reconsideration. The notice must include the reason for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the decision to grant an extension.

(4) *Notice of resolution*. The applicable integrated plan must send a written notice to enrollees that includes the integrated reconsidered determination, within the resolution timeframes set forth in this section. The notice of determination must be written in plain language and available in a language and format that is accessible to the enrollee and must explain the following:

(i) The resolution of and basis for the integrated reconsideration and the date it was completed.

(ii) For integrated reconsiderations not resolved wholly in favor of the enrollee:

(A) An explanation of the next level of appeal available under the Medicare and Medicaid programs, and what steps the enrollee must take to pursue the next level of appeal under each program, and how the enrollee can obtain assistance in pursuing the next level of appeal under each program; and

(B) The right to request and receive Medicaid-covered benefits while the next level of appeal is pending, if applicable.

(g) *Withdrawing a request*. The party or physician acting on behalf of an enrollee who files a request for integrated reconsideration may withdraw it by filing a request for withdrawal with the applicable integrated plan.

(h) *Dismissing a request*. The applicable integrated plan dismisses an expedited or standard integrated reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting an integrated reconsideration is not a proper party to request an integrated reconsideration under § 422.629(*l*).

(2) The applicable integrated plan determines the party failed to make a valid request for an integrated reconsideration that substantially complies with § 422.629(*l*) of this section.

(3) The party fails to file the integrated reconsideration request within the proper filing timeframe in accordance with paragraph (d) of this section.

(4) The enrollee or the enrollee's representative files a request for an integrated reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated reconsideration.

(5) A party filing the reconsideration request submits a timely request for withdrawal of their request for an integrated reconsideration with the applicable integrated plan.

(i) *Notice of dismissal*. The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(j) *Vacating a dismissal*. If good cause is established, the applicable integrated plan may vacate its dismissal of a request for integrated reconsideration within 6 months from the date of the notice of dismissal.

(k) *Effect of dismissal*. The applicable integrated plan's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the

dismissal is vacated under paragraph (j) of this section.

[84 FR 15835, Apr. 16, 2019, as amended at 84 FR 23883, May 23, 2019; 84 FR 26579, June 7, 2019; 86 FR 6103, Jan. 19, 2021; 87 FR 27897, May 9, 2022]

§ 422.634 Effect.

(a) *Failure of the applicable integrated plan to send timely notice of a determination.* If the applicable integrated plan fails to adhere to the notice and timing for an integrated organization determination or integrated reconsideration, this failure constitutes an adverse determination for the enrollee.

(1) For an integrated organization determination, this means that the enrollee may request an integrated reconsideration.

(2) For integrated reconsiderations of Medicare benefits, this means the applicable integrated plan must forward the case to the independent review entity, in accordance with the timeframes under paragraph (b) of this section and § 422.592. For integrated reconsiderations of Medicaid benefits, this means that an enrollee or other party may file for a State fair hearing in accordance with § 438.408(f) of this chapter, or if applicable, a State external medical review in accordance with § 438.402(c) of this chapter.

(b) *Adverse integrated reconsiderations.* (1) Subject to paragraph (b)(2) of this section, when the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicare benefit—

(i) The issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS, in accordance with §§ 422.592 and 422.594 through 422.619;

(ii) For standard integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review 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 (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity; and

(iii) For expedited integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than within 24 hours of its affirmation (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(2) When the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicaid benefit, the enrollee or other party (that is not the applicable integrated plan) may initiate a State fair hearing in the timeframe specified in § 438.408(f)(2) following the integrated plan's notice of resolution. If a provider is filing for a State fair hearing on behalf of the enrollee as permitted by State law, the provider needs the written consent of the enrollee, if he or she has not already obtained such consent.

(c) *Final determination.* The reconsidered determination of the applicable integrated plan is binding on all parties unless it is appealed to the next applicable level. In the event that the enrollee pursues the appeal in multiple forums and receives conflicting decisions, the applicable integrated plan is bound by, and must act in accordance with, decisions favorable to the enrollee.

(d) *Services not furnished while the appeal is pending.* (1) If an applicable integrated plan reverses its decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than the earlier of—

(i) 72 hours from the date it reverses its decision; or

(ii)(A) With the exception of a Part B drug, 30 calendar days after the date the applicable integrated plan receives

the request for the integrated reconsideration (or no later than upon expiration of an extension described in § 422.633(f)); or

(B) For a Part B drug, 7 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration.

(2) For a Medicaid benefit, if a State fair hearing officer reverses an applicable integrated plan's integrated reconsideration decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(3) Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

(e) *Services furnished while the appeal is pending.* If the applicable integrated plan or the State fair hearing officer reverses a decision to deny, limit, or delay Medicaid-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan or the State must pay for those services, in accordance with State policy and regulations. If the applicable integrated plan reverses a decision to deny, limit, or delay Medicare-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan must pay for those services.

[63 FR 35107, June 26, 1998, as amended at 87 FR 27898, May 9, 2022]

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 not to authorize a renewal of a contract with an MA organization in accordance with § 422.506(b).

(c) A determination to terminate a contract with an MA organization in accordance with § 422.510(a).

(d) A determination that an entity is not qualified to offer a Specialized MA Plan for Special Needs Individuals as defined in §§ 422.2 and 422.4(a)(1)(iv).

[63 FR 35113, June 26, 1998, as amended at 77 FR 22168, Apr. 12, 2012; 80 FR 7962, Feb. 12, 2015]

§ 422.644 Notice of contract determination.

(a) When CMS makes a contract determination under § 422.641, it gives the MA organization written notice.

(b) The notice specifies—

(1) Reasons for the determination; and

(2) The MA organization's right to request a hearing.

(c) *CMS-initiated terminations*—(1) *General rule.* Except as provided in paragraph (c)(2) of this section, CMS mails notice to the MA organization 45 calendar days before the anticipated effective date of the termination.

(2) *Exception.* If a contract is terminated in accordance with § 422.510(b)(2)(i) of this part, CMS notifies the MA organization of the date that it will terminate the MA organization's contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the MA organization by August 1 of the current contract year.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68724, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010; 80 FR 7962, Feb. 12, 2015]

§ 422.646 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under 422.662.

[72 FR 68724, Dec. 5, 2007]

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part C of Title XVIII of the Act in accordance with §§ 422.501 and 422.502.

(2) An MA organization whose contract has been terminated in accordance with § 422.510.

(3) An MA organization whose contract has not been renewed in accordance with § 422.506.

(4) An MA organization who has had an intermediate sanction imposed in accordance with § 422.752(a) through (b) of this part.

(5) An applicant that has been determined to be unqualified to offer a Specialized MA Plan for Special Needs Individuals.

(b) *Burden of proof, standard of proof, and standards of review at a hearing.* (1) During a hearing to review a contract determination as described at § 422.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§ 422.501 and 422.502 of this part.

(2) During a hearing to review a contract determination as described at § 422.641(b) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.506 of this part.

(3) During a hearing to review a contract determination as described at § 422.641(c) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.510 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 422.750, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.752(a) and (b).

(5) During a hearing to review a determination as described at § 422.641(d) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

(c) *Timing of favorable decisions.* Notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

[75 FR 19813, Apr. 15, 2010, as amended at 77 FR 22168, Apr. 12, 2012; 80 FR 7962, Feb. 12, 2015]

§ 422.662 Request for hearing.

(a) *Method and place for filing a request.* (1) 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 the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

(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; 72 FR 68724, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010]

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

(a) *Hearing.* When a request for a hearing is timely filed, CMS will postpone the proposed effective date of the contract determination listed at 422.641 until a hearing decision is reached and affirmed by the Administrator following review according to 422.692 in instances where an MA organization or CMS requests Administrator review and the Administrator accepts the matter for review.

(b) *Exceptions:* (1) If a final decision is not reached on CMS' determination for an initial contract by September 1, CMS will not enter into a contract with the applicant for the following year.

(2) A contract terminated in accordance with § 422.510(b)(2)(i) of this part will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

[72 FR 68724, Dec. 5, 2007, as amended at 75 FR 19813, Apr. 15, 2010; 83 FR 16734, Apr. 16, 2018]

§ 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—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of the request for the hearing; and

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The MA organization or CMS may request an extension by filing a written request no later than 10 calendar days prior to the scheduled hearing.

(2) When either the MA organization or CMS requests an extension, the hearing officer will provide a one-time 15 calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

[75 FR 19813, Apr. 15, 2010]

§ 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 MA organization bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

[63 FR 35113, June 26, 1998, as amended at 75 FR 19813, Apr. 15, 2010]

§ 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 Witness lists and documents.

Witness lists and documents must be identified and exchanged at least 5 calendar days before the scheduled hearing.

[75 FR 19813, Apr. 15, 2010]

§ 422.684 Prehearing and summary judgment.

(a) *Prehearing.* The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

(b) *Summary judgment.* Either party to the hearing may ask the hearing officer to rule on a motion for summary judgment.

[72 FR 68725, Dec. 5, 2007]

§ 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.* CMS or an MA organization that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 422.690(b). Both the MA organization and CMS may provide written arguments to the Administrator for review.

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing decision in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator

does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, 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 or CMS, whether the determination should be upheld, reversed, or modified.

(e) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the MA organization requesting review.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68725, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010]

§ 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 a contract determination or decision of a hearing officer or the Administrator.

(a) *Contract determination.* CMS may reopen and revise an initial determination upon its own motion.

(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.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68725, Dec. 5, 2007; 75 FR 19814, Apr. 15, 2010]

Subpart O—Intermediate Sanctions

SOURCE: 63 FR 35115, June 26, 1998, unless otherwise noted.

§ 422.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the MA organization's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the MA organization for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of communication activities to Medicare beneficiaries by an MA organization, as defined by CMS.

(b) CMS may impose civil money penalties as specified in 422.760.

[72 FR 68725, Dec. 5, 2007, as amended at 75 FR 19814, Apr. 15, 2010; 83 FR 16734, Apr. 16, 2018]

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph, CMS may impose one or more of the sanctions specified in § 422.750(a) of this subpart on any MA organization with a contract. The MA organization may also be subject to other remedies authorized under law.

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

(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) Acts to expel or refuses to re-enroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization 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.

(9) Except as provided under §423.34 of this chapter, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual.

(10) Transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission.

(11) Fails to comply with communication restrictions described in subpart V of this part or applicable implementing guidance.

(12) Employs or contracts with any individual, agent, provider, supplier or entity who engages in the conduct described in paragraphs (a)(1) through (11) of this section.

(13) Fails to comply with §§422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals and entities, nor to individuals and entities on the preclusion list, defined in §422.2.

(b) *Suspension of enrollment and communications.* If CMS makes a determination that could lead to a contract termination under §422.510(a), CMS may impose the intermediate sanctions at §422.750(a)(1) and (3).

(c) *Civil Money Penalties.* (1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in the following:

(i) Section 422.760(b) for any of the determinations at §422.510(a), except §422.510(a)(4)(i).

(ii) Section 422.760(c) for any of the determinations at §422.752(a) except §422.752(a)(5).

(2) *OIG.* In addition to, or in place of any intermediate sanctions imposed by CMS, the OIG, in accordance with part 1003 of Chapter V of this title, may impose civil money penalties for the following:

(i) Violations listed at 422.752(a).

(ii) Determinations made under §422.510(a)(4)(i).

(d) *Special rule for non-compliant dual eligible special needs plans.* Notwithstanding any other provision of this section, CMS must impose during plan years 2021 through 2025 intermediate sanctions specified at §422.750(a) on an MA organization with a contract to operate a dual eligible special needs plan if CMS determines that the dual eligible special needs plan fails to comply with at least one of the criteria for the integration of Medicare and Medicaid benefits provided in the definition of a dual eligible special needs plan at §422.2. If CMS imposes such an intermediate sanction, the MA organization must submit to CMS a corrective action plan in a form, manner, and timeframe established by CMS. The procedures outlined in §422.756 apply to the

imposition of the intermediate sanction under this provision.

[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; 72 FR 68725, Dec. 5, 2007; 75 FR 19814, Apr. 15, 2010; 79 FR 29959, May 23, 2014; 81 FR 80557, Nov. 15, 2016; 83 FR 16734, Apr. 16, 2018; 84 FR 15839, April 16, 2019]

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) *Notice of intermediate sanction and opportunity to respond*—(1) *Notice of intent*. Before imposing the intermediate sanction, CMS—

(i) Sends a written notice to the MA organization stating the nature and basis of the proposed intermediate sanction and the MA organization's right to a hearing as specified in paragraph (b) of this section; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond*. CMS allows the MA organization 10 calendar days after receipt of the notice to provide a written rebuttal. CMS considers receipt of the notice as the day after notice is sent by fax, e-mail, or submitted for overnight mail.

(b) *Hearing*. (1) The MA organization may request a hearing before a CMS hearing officer.

(2) A written request must be received by the designated CMS office within 15 calendar days after the receipt of the notice.

(3) A request for a hearing under § 422.660 does not delay the date specified by CMS when the sanction becomes effective.

(4) The MA organization must follow the right to a hearing procedure as specified at subpart N of this part..

(c) *Effective date and duration of sanctions*—(1) *Effective date*. The effective date of the sanction is the date specified by CMS in the notice.

(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 an earlier date that CMS specifies.

(3) *Duration of sanction*. The sanction remains in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur.

(i) CMS may require that the MA organization hire an independent auditor to provide CMS with additional information to determine if the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

(ii) In instances where intermediate sanctions have been imposed, CMS may require an MA organization to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur.

(A) If, following this time period, CMS determines the deficiencies have not been corrected or are likely to recur, the intermediate sanctions will remain in effect until such time that CMS is assured the deficiencies have been corrected and are not likely to recur.

(B) The MA organization does not have a right to a hearing under § 422.660(a)(4) of this part to challenge CMS' determination to keep the intermediate sanctions in effect.

(C) During the limited time period, sanctioned sponsoring organizations offering Part D plans under the benchmark that would normally participate in the annual and monthly auto enrollment process for enrollees receiving the low income subsidy will not be allowed to receive or process these types of enrollments.

(d) *Non-renewal or termination by CMS*. In addition to or as an alternative to the sanctions described in § 422.750, CMS may—

(1) Decline to authorize the renewal of an organization's contract in accordance with § 422.506(b); or

(2) Terminate the contract in accordance with § 422.510.

(e) Notice to impose *civil money penalties*—(1) *CMS notice to OIG*. If CMS determines that an MA organization has failed to comply with a requirement as

described in 422.752, CMS notifies the OIG of this determination. OIG may impose a civil money penalty upon an MA organization as specified at 422.752(c)(2).

(2) *CMS notice of civil money penalties to MA organizations.* If CMS makes a determination to impose a CMP as described in 422.752(c)(1), CMS will send a written notice of the Agency's decision to impose a civil money penalty to include—

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The MA organization's right to a hearing under subpart T of this part.

(vi) Information about where to file the request for hearing.

[63 FR 35113, June 26, 1998, as amended at 68 FR 50859, Aug. 22, 2003; 70 FR 4741, Jan. 28, 2005; 72 FR 68725, Dec. 5, 2007; 73 FR 55764, Sept. 26, 2008; 75 FR 19814, Apr. 15, 2010; 79 FR 29959, May 23, 2014]

§ 422.758 Collection of civil money penalties imposed by CMS.

(a) When an MA organization does not request a hearing, CMS initiates collection of the civil money penalty following the expiration of the timeframe for requesting an ALJ hearing as specified in subpart T of this part.

(b) If an MA organization requests a hearing and CMS' decision to impose a civil money penalty is upheld, CMS may initiate collection of the civil money penalty once the administrative decision is final.

[72 FR 68726, Dec. 5, 2007]

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) *Determining the appropriate amount of any penalty.* In determining the amount of penalty imposed under 422.752(c)(1), CMS will consider as appropriate:

(1) The nature of the conduct;

(2) The degree of culpability of the MA organization;

(3) The adverse effect to enrollees which resulted or could have resulted from the conduct of MA organization;

(4) The financial condition of the MA organization;

(5) The history of prior offenses by the MA organization or principals of the MA organization; and,

(6) Such other matters as justice may require.

(b) *Amount of penalty imposed by CMS.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more MA enrollees—up to $25,000 as adjusted annually under 45 CFR part 102 for each determination.

(2) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more MA enrollees, CMS may calculate a CMP of up to $25,000 as adjusted annually under 45 CFR part 102 for each MA enrollee directly adversely affected (or with the substantial likelihood of being adversely affected) by a deficiency.

(3) CMS calculates the minimum penalty amounts under paragraphs (b)(1) and (2) of this section using the following criteria:

(i) *Definitions for calculating penalty amounts*—(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(E) *Cost-of-living multiplier.* The percent change between each year's published October consumer price index for all urban consumers (United States city average), which is released by The Office of Management and Budget (OMB) annually.

(ii) *Calculation of minimum penalty amounts.* (A) Per determination and per enrollee minimum penalty amounts are increased by multiplying the current standard minimum penalty and

aggravating factor amounts by the cost-of-living multiplier.

(B) The minimum penalty and aggravating factor amounts is updated no more often than every 3 years.

(C) CMS tracks the calculation and accrual of the standard minimum penalty and aggravating factor amounts and announces them on an annual basis.

(4) For each week that a deficiency remains uncorrected after the week in which the MA organization receives CMS' notice of the determination—up to $10,000 as adjusted annually under 45 CFR part 102.

(5) 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 as adjusted annually under 45 CFR part 102 per Medicare enrollee from the terminated MA plan or plans at the time the MA organization terminated its contract, or $100,000 as adjusted annually under 45 CFR part 102, whichever is greater.

(c) *Amount of penalty imposed by CMS or OIG.* CMS or the OIG may impose civil money penalties in the following amounts for a determination made under § 422.752(a):

(1) Civil money penalties of not more than $25,000 as adjusted annually under 45 CFR part 102 for each determination made.

(2) With respect to a determination made under § 422.752(a)(4) or (a)(5)(i), not more than $100,000 as adjusted annually under 45 CFR part 102 foreach such determination, except with respect to a determination made under § 422.752(a)(5), an assessment of not more than the amount claimed by such plan or MA organization based upon the misrepresentation or falsified information involved.

(3) Plus with respect to a determination made under § 422.752(a)(2), double the excess amount charged in violation of such paragraph (and the excess amount charged must be deducted from the penalty and returned to the individual concerned).

(4) Plus with respect to a determination made under § 422.752(a)(4), $15,000 as adjusted annually under 45 CFR part 102 for each individual not enrolled as a result of the practice involved.

[72 FR 68726, Dec. 5, 2007, as amended at 74 FR 1542, Jan. 12, 2009; 79 FR 29960, May 23, 2014; 81 FR 61562, Sept. 8, 2016; 86 FR 6103, Jan. 19, 2021; 86 FR 29528, June 2, 2021]

§ 422.762 Settlement of penalties.

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

[72 FR 68726, Dec. 5, 2007]

§ 422.764 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.

[63 FR 35115, June 26, 1998. Redesignated at 72 FR 68726, Dec. 5, 2007]

Subparts P–S [Reserved]

Subpart T—Appeal procedures for Civil Money Penalties

SOURCE: 72 FR 68726, Dec. 5, 2007, unless otherwise noted.

§ 422.1000 Basis and scope.

(a) *Statutory basis.* (1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857(g) of the Act provides that, for MA organizations out of compliance with the requirements in part 422 specified remedies may be imposed instead of, or in addition to, termination of the MA organization's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on MA organizations.

(b) [Reserved]

§ 422.1002 Definitions.

As used in this subpart—

Affected party means an MA organization impacted by an initial determination or if applicable, by any subsequent determination or decision issued under this part. For this definition, ''*party*'' means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

MA organization has the meaning given the term in 422.2.

§ 422.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 422, subpart O.

§ 422.1006 Appeal rights.

(a) *Appeal rights of MA organizations.* (1) Any MA organization dissatisfied with an initial determination as specified in 422.1004, has a right to a hearing before an ALJ in accordance with this subpart and may request Departmental Appeals Board review of the ALJ decision.

(2) MA organizations may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.

(b) [Reserved]

§ 422.1008 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with the ALJ or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 422.1010 Authority of representatives.

(a) A representative appointed and qualified in accordance with 422.1008 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 422.1012 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with 422.1008 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 422.1014 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

§ 422.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and 1 copy to the ALJ or the Departmental Appeals Board, as appropriate.

The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 calendar days from the date of mailing or in person filing to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and 1 copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

[72 FR 68726, Dec. 5, 2007, as amended at 79 FR 29960, May 23, 2014]

§ 422.1018 Notice and effect of initial determinations.

(a) *Notice of initial determination.* CMS, as required under 422.756(f)(2), mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to a hearing, and information about where to file the request for hearing.

(b) *Effect of initial determination.* An initial determination is binding unless—

(1) The affected party requests a hearing; or

(2) CMS revises its decision.

§ 422.1020 Request for hearing.

(a) *Manner and timing of request.* (1) An MA organization is entitled to a hearing as specified in 422.1006 and may file a request for a hearing with the Departmental Appeals Board office specified in the initial determination.

(2) The MA organization or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days after receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for each contention that the finding or conclusion of law is incorrect.

[72 FR 68726, Dec. 5, 2007, as amended at 79 FR 29960, May 23, 2014]

§ 422.1022 Parties to the hearing.

The parties to the hearing are the affected party and CMS, as appropriate.

§ 422.1024 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board, or his or her delegate designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Chair or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, ''ALJ'' includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 422.1026 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another ALJ will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 422.1028 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying

the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 422.1030 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 calendar days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 422.1032 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 422.1034 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.* (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 calendar days to file objections to the order.

(3) After the 10 calendar days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 422.1036 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 calendar days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 422.1038 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 422.1040 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree,

fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.

§ 422.1042 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS has not made initial determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Notice and conduct of hearing on new issues.* (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with 422.1036.

(2) After giving notice, the ALJ will, except as provided in paragraph (c) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(c) *Remand to CMS.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (b) of this section, the ALJ may remand the case to CMS for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS to return the case to the ALJ for further proceedings.

§ 422.1044 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 calendar days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary.

§ 422.1046 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(4) CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and legal authority) to establish a prima facie case that CMS has a legally sufficient basis for its determination.

(5) The affected party has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

(6) The affected party bears the ultimate burden of persuasion. To prevail, the affected party must prove by a preponderance of the evidence on the record as a whole that there is no basis for the determination.

(c) *Review of the penalty.* When an administrative law judge finds that the

basis for imposing a civil money penalty exists, as specified in 422.752, the administrative law judge may not—

(1) Set a penalty of zero or reduce a penalty to zero, or

(2) Review the exercise of discretion by CMS to impose a civil money penalty.

§ 422.1048 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 422.1050 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 422.1052 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with 422.1016.

§ 422.1054 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 422.1056 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with 422.1060.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) Handling of briefs and related statements. If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with 422.1016.

§ 422.1058 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 422.1060 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 calendar days after the ALJ sends a ''show cause'' notice, with a showing of good cause.

§ 422.1062 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata*. There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing*. The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed*. The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 422.1064 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in 422.1066.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 422.1066 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 calendar days from receipt of the notice of dismissal and shows good cause for vacating the dismissal.

§ 422.1068 Administrative Law Judge's decision.

(a) *Timing, basis and content*. As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect*. A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in 422.846, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Departmental Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

§ 422.1070 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 422.1072 Remand by the Administrative Law Judge.

(a) If CMS requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

§ 422.1074 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 422.1076 Request for Departmental Appeals Board review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the DAB within 60 calendar days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing.

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 422.1078 Departmental Appeals Board action on request for review.

(a) *Request by CMS.* The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Board may deny or grant the affected party's request for review or may dismiss the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel.* If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of three members of the Board, designated by the Chair or Deputy Chair.

§ 422.1080 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with 422.1016.

§ 422.1082 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

§ 422.1084 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take

other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 calendar days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-calendar day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 422.1086 Effect of Departmental Appeals Board Decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with 422.862.

(b) *Right to judicial review.* Section 422.1006 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special Rules:* Civil Money Penalty—Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-day period for seeking judicial review.

§ 422.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with a Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 calendar days from receipt of the notice of the Board's decision, unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-calendar day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 422.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 calendar days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 422.1092 Revision of reopened decision.

(a) *Revision based on new evidence.* If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 422.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in 423.1088.

[72 FR 68726, Dec. 5, 2007, as amended at 85 FR 72909, Nov. 16, 2020]

Subpart U [Reserved]

Subpart V—Medicare Advantage Communication Requirements

SOURCE: 73 FR 54220, Sept. 18, 2008, unless otherwise noted.

§ 422.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for, or call to attention. Advertisements can be considered communications or marketing based on the intent and content of the message.

Alternate format means a format used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the MA plan (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the internet).

Communications means activities and use of materials created or administered by the MA organization or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended, as determined under paragraph (1)(ii) of this definition, to do any of the following:

(i)(A) Draw a beneficiary's attention to a MA plan or plans.

(B) Influence a beneficiary's decision-making process when making a MA plan selection.

(C) Influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).

(ii) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the MA organization's stated intent.

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums, or cost sharing.

(ii) Measuring or ranking standards (for example, Star Ratings or plan comparisons).

(iii) Rewards and incentives as defined under § 422.134(a).

Outdoor advertising (ODA) means outdoor material intended to capture the

attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be communications or marketing material.

Third-party marketing organization (TPMO) means organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of an MA plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 422.2, but may also be entities that are not FDRs but provide services to an MA plan or an MA plan's FDR.

[86 FR 6103, Jan. 19, 2021, as amended at 87 FR 27898, May 9, 2022]

§ 422.2261 Submission, review, and distribution of materials.

(a) *General requirements.* MA organizations must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS Marketing Module by the MA organization or, where materials have been developed by a Third Party Marketing Organization for multiple MA organizations or plans, by a Third Party Marketing Organization with prior review of each MA organization on whose behalf the materials were created or will be used.

(b) *CMS review of marketing materials and election forms.* MA organizations may not distribute or otherwise make available any marketing materials or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e) of this chapter) of submission to CMS; or

(3) The material has been accepted under File and Use, as follows:

(i) The MA organization may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The MA organization must certify that the material meets all applicable CMS communications and marketing requirements in §§ 422.2260 through 422.2267.

(c) *CMS review of non-marketing communications materials.* CMS does not require submission, or submission and approval, of communications materials prior to use, other than the following exceptions.

(1) Certain designated communications materials that are critical to beneficiaries understanding or accessing their benefits (for example, the Evidence of Coverage (EOC).

(2) Communications materials that, based on feedback such as complaints or data gathered through reviews, warrant additional oversight as determined by CMS, to ensure the information being received by beneficiaries is accurate.

(d) *Standards for CMS review.* CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 422.2260 through 422.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the MA organization's bid.

(3) CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

[86 FR 6104, Jan. 19, 2021, as amended at 88 FR 22335, Apr. 12, 2023]

§ 422.2262 General communications materials and activities requirements.

MA organizations may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees.

(a) *General rules.* MA organizations must ensure their statements and the

terminology used in communications activities and materials adhere to the following requirements:

(1) MA organizations may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Use of superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the material. Such supportive documentation or data must reflect data, reports, studies, or other documentation that applies to the current or prior contract year.

(A) Including data older than the prior contract year is permitted provided the current and prior contract year data are specifically identified.

(B) [Reserved]

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on income levels, unless it is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(vi) Target potential enrollees based on health status, unless it is a special needs plan or comparable plan as determined by the Secretary.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries, unless it is a special needs plan or comparable plan as determined by the Secretary. This prohibition does not apply to MA plan names in effect prior to July 31, 2000.

(ix) Display the names or logos or both of co-branded network providers on the organization's member identification card, unless the provider names or logos or both are related to the member selection of specific provider organizations (for example, physicians or hospitals).

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, ''Super Medicare Advantage (HMO).'' MA organizations are not required to repeat the plan type when the plan name is used multiple times in the same material.

(xi) Claim they are recommended or endorsed by CMS, Medicare, the Secretary, or HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment, except for factually accurate descriptions of the MA organization's policies adopted in accordance with § 422.74(b)(1) and (d)(1) of this chapter.

(xiii) Use the term ''free'' to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing pertaining to dual eligible individuals.

(xiv) Imply that the plan operates as a supplement to Medicare.

(xv) State or imply a plan is available only to or is designed for beneficiaries who are dually eligible for Medicare and Medicaid, unless it is a dual-eligible special needs plan or comparable plan as determined by the Secretary.

(xvi) Market a non-dual eligible special needs plan as if it were a dual-eligible special needs plan.

(xvii) Target marketing efforts primarily to dual eligible individuals, unless the plan is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(xviii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for enrollees in that plan is in place.

(xix) Use the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card, in a misleading way. Use of the Medicare card image is permitted only with authorization from CMS.

(2) MA organizations may do the following:

(i) State that the MA organization is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term ''Medicare-approved'' to describe benefits or services in materials or both.

(iii) Use the term ''free'' in conjunction with mandatory, supplemental, and preventative benefits provided at a zero cost share for all enrollees.

(b) *Product endorsements and testimonials.* (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the MA organization, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) MA organizations may use individuals to endorse the MA organization's product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the MA organization's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the MA organization must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the endorsement or testimonial must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) MA organizations must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a MA organization includes its customer service number, the hours of operation must be prominently included at least once.

(ii) When a MA organization includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1–800–MEDICARE or Medicare TTY appears, the MA organization must prominently include, at least once, the hours and days of operation for 1–800–MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) MA organizations must use a standardized method of identification for oversight and tracking of materials received by beneficiaries.

(2) The SMID consists of the following three parts:

(i) The MA organization contract or Multi-Contract Entity (MCE) number (that is, ''H'' for MA or Section 1876 Cost Plans, ''R'' for Regional PPO plans (RPPOs), or ''Y'' for MCE, a means of identification available for Plans/Part D sponsors that have multiple MA contracts) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word ''MULTI–PLAN'' instead of the MA organization's contract number (for example, H1234_abc123_C or MULTI–PLAN_efg456_M).

(ii) A series of alpha numeric characters (chosen at the MA organization's discretion) unique to the material followed by an underscore.

(iii) An uppercase ''C'' for communications materials or an uppercase ''M'' for marketing materials (for example, H1234_abc123_C or H5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials specified in § 422.2267.

(iv) Corporate notices or forms (that is, not MA/Part D specific) meeting the definition of communications (see § 422.2260) such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created

materials, may have the same SMID as the material on which they are based.

[86 FR 6104, Jan. 19, 2021, as amended at 88 FR 22335, Apr. 12, 2023]

§ 422.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 422.2262 as well as this section. Marketing (as defined in § 422.2260) must additionally meet the following requirements:

(a) MA organizations may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. MA organizations may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, MA organizations may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to beneficiaries, unless the gifts are of nominal value (as governed by guidance published by the HHS OIG), are offered to similarly situated beneficiaries without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any MA sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the MA organization making the comparison.

(6) Display the names or logos or both of provider co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that ''Other providers are available in the network.''

(7) Knowingly target or send unsolicited marketing materials to any MA enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, an MA organization may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first 9 months of the year;

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent;

(D) At the beneficiary's request, provide information on the OEP through the call center; and

(E) Include educational information, excluding marketing, on the MA organization's website about the existence of OEP.

(ii) During the OEP, an MA organization may not:

(A) Send unsolicited materials advertising the ability or opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent or broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(8) Advertise benefits that are not available to beneficiaries in the service area(s) where the marketing appears, unless the advertisement is in local media that serves the service area(s) where the benefits are available and reaching beneficiaries who reside in other service areas is unavoidable.

(9) Market any products or plans, benefits, or costs, unless the MA organization or marketing name(s) as listed in HPMS of the entities offering the referenced products or plans, benefits, or costs are identified in the marketing material.

(i) MA organization or marketing names must be in 12-point font in print

and may not be in the form of a disclaimer or fine print.

(ii) For television, online, or social media, the MA organization or marketing name(s) must be either read at the same pace as the phone number or must be displayed throughout the entire advertisement in a font size equivalent to the advertised phone number, contact information, or benefits.

(iii) For radio or other voice-based advertisements, MA organization or marketing names must be read at the same pace as the advertised phone numbers or other contact information.

(10) MA organizations may not include information about savings available to potential enrollees that are based on a comparison of typical expenses borne by uninsured individuals, unpaid costs of dually eligible beneficiaries, or other unrealized costs of a Medicare beneficiary.

(c) The following requirements apply to how MA organizations must display CMS-issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the overall Star Rating for MA–PDs and the summary rating for MA-only plans.

(2) May not use an individual underlying category, domain, or measure rating to imply overall higher Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Ratings contract year.

(5) May only market the Star Ratings in the service area(s) for which the Star Rating is applicable, unless using Star Ratings to convey overall MA organization performance (for example, ''Plan X has achieved 4.5 stars in Montgomery, Chester, and Delaware Counties), in which case the MA organization must do so in a way that is not confusing or misleading.

(6) The following requirements apply to all 5 Star MA contracts:

(i) May not market the 5-star special enrollment period, as defined in § 422.62(b)(15), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5-star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the MA organization's contract received a summary rating of 2.5 stars or below in Part C or Part D or both for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

[86 FR 6105, Jan. 19, 2021, as amended at 88 FR 22335, Apr. 12, 2023]

§ 422.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact means any outreach activities to a beneficiary or a beneficiary's caregivers by the MA organization or its agents and brokers.

(a) *Unsolicited contact.* Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) MA organizations may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) MA organizations may not do any of the following if unsolicited:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(A) Contact is unsolicited door-to-door contact unless an appointment, at the beneficiary's home at the applicable date and time, was previously scheduled.

(B) [Reserved]

(ii) Approach enrollees in common areas such as parking lots, hallways, and lobbies.

(iii) Send direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), robocalls, text messages, or voicemail messages, including, but not limited to, the following:

(A) Calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has completed a business reply card requesting contact is not considered unsolicited.

(b) *Contact for plan business.* MA organizations may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) An MA organization may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in a Part D plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing due to reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark; and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) MA organizations may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) If the MA organization reaches out to beneficiaries regarding plan business, as outlined in this section, the MA organization must provide notice to all beneficiaries whom the plan contacts as least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business.

(c) *Events with beneficiaries.* MA organizations and their agents or brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, MA organizations and agents/brokers may not market specific MA plans or benefits.

(ii) MA organizations holding or participating in educational events may do any of the following:

(A) Distribute communications materials.

(B) Answer beneficiary-initiated questions pertaining to MA plans.

(C) Distribute business cards.

(D) Make available and receive beneficiary contact information, including Business Reply Cards, but not including Scope of Appointment forms.

(iii) MA organizations holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(iv) MA organizations may schedule appointments with residents of long-term care facilities (for example, nursing homes, assisted living facilities, board and care homes) upon a resident's request. If a resident did not request an appointment, any visit by an agent or broker is prohibited as unsolicited door-to-door marketing.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 422.2260.

(i) Marketing events are prohibited from taking place within 12 hours of an educational event, in the same location. The same location is defined as the entire building or adjacent buildings.

(ii) MA organizations holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) MA organizations holding or participating in marketing events may not do any of the following:

(A) Require sign-in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is, ''cherry-picking'').

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) At least 48 hours prior to the scheduled personal marketing, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies), except for:

(A) SOAs that are completed during the last four days of a valid election period for the beneficiary.

(B) Unscheduled in person meetings (walk-ins) initiated by the beneficiary.

(ii) MA organizations holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) MA organizations holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan in a Scope of Appointment, business reply card, or request to receive additional information, which is valid for 12 months following the date of beneficiary's signature date or the date of the beneficiary's initial request for information.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment, identifying the additional lines of business to be discussed; such Scope of Appointment is valid for 12 months following the beneficiary's signature date.

(C) Market non-health related products, such as annuities.

[86 FR 6106, Jan. 19, 2021, as amended at 88 FR 22335, Apr. 12, 2023]

§ 422.2265 Websites.

As required under § 422.111(h)(2), MA organizations must have a website.

(a) *General website requirements.* (1) MA organization websites must meet all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the MA organization's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable notices, statements, disclosures, or disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Reflect the most current information within 30 days of any material change.

(v) Keep MA content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) MA organization websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the MA organization is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the MA organization.

(b) *Required content.* MA organization's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable provider directory.

(4) A provider directory searchable by every element required in the model provider directory, such as name, location, specialty.

(5) When applicable, a searchable pharmacy directory combined with a provider directory.

(6) Information on enrollees' and MA organizations' rights and responsibilities upon disenrollment. MA organizations may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, request an organization determination, and an appeal.

(8) Prominently displayed link to the Medicare.gov electronic complaint form.

(9) Disaster and emergency policy consistent with § 422.100(m)(5)(iii).

(10) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(11) For PFFS plans, a link to the PFFS Terms and Conditions of Payment.

(12) For MSA plans, the following statements:

(i) ''You must file Form 1040, 'US Individual Income Tax Return,' along with Form 8853, 'Archer MSA and Long-Term Care Insurance Contracts' with the Internal Revenue Service (IRS) for any distributions made from your Medicare MSA account to ensure you aren't taxed on your MSA account withdrawals. You must file these tax forms for any year in which an MSA account withdrawal is made, even if you have no taxable income or other reason for filing a Form 1040. MSA account withdrawals for qualified medical expenses are tax free, while account withdrawals for non-medical expenses are subject to both income tax and a fifty (50) percent tax penalty.''

(ii) ''Tax publications are available on the IRS website at *http://www.irs.gov* or from 1–800–TAX–FORM (1–800–829–3676).''

(13) Instructions on how to appoint a representative including a link to the downloadable version of the CMS Appointment of Representative Form (CMS Form–1696).

(14) Enrollment instructions and forms.

(c) *Required posted materials.* MA organization's website must provide access to the following materials, in a printable format, within the timeframes specified in paragraphs (c)(1) and (2) of this section.

(1) The following materials for each plan year must be posted on the website by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Provider Directory.

(v) Provider/Pharmacy Directory.

(2) The following materials must be posted on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for physicians and enrollees.

(ii) When applicable, Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

[86 FR 6107, Jan. 19, 2021, as amended at 87 FR 27898, May 9, 2022; 88 FR 22336, Apr. 12, 2023]

§ 422.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and clinical team (including such areas in dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including the following:

(1) Common entryways.

(2) Vestibules.

(3) Waiting rooms.

(4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities.* Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the MA organization or pursuant to the network participation agreement between the MA organization and the provider. Provider-initiated activities that meet the definition in this paragraph (c) fall outside of the definition of marketing in § 422.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the ''Medicare & You'' handbook, or ''Medicare Options Compare'' (from *https://www.medicare.gov*), including in areas where care is delivered.

(2) Providing the names of MA organizations with which they contract or participate or both.

(3) Answering questions or discussing the merits of a MA plan or plans, including cost sharing and benefit information, including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at *https://www.medicare.gov*, or 1–800–MEDICARE.

(5) Referring patients to MA plan marketing materials available in common areas;

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with MA organizations, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities.* Plan-initiated provider activities are those activities conducted by a provider at the request of an MA organization. During a plan-initiated provider activity, the provider is acting on behalf of the MA organization. For the purpose of plan-initiated activities, the MA organization is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, MA organizations must ensure that the provider does not:

(i) Accept or collect Scope of Appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of the MA organization.

(v) Offer inducements to persuade patients to enroll in a particular MA plan or organization.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the MA organization for any marketing or enrollment activities performed on behalf of the MA organization.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *MA organization activities in the health care setting.* MA organization activities in the health care setting are those activities, including marketing activities that are conducted by MA organization staff or on behalf of the MA organization, or by any downstream entity, but not by a provider. All marketing must comply with the requirements in paragraphs (a) and (b) of this section. However, during MA organization activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

(f) *Activities of Institutional Special Needs Plans (I–SNPs) Serving Long-Term Care Facility Residents* (1) Depending on the context of a given situation, I–SNP contracted with a long-term care facility can be viewed as both a provider and a plan.

(2) I–SNPs may use staff operating in a social worker capacity to provide information, including marketing materials (excluding enrollment forms), to residents of a long term care facility.

(3) Social workers of the I–SNP (whether employees, agents, or contracted providers) may not accept or collect a scope of appointment or enrollment form on behalf of the I–SNP.

(4) Unless the beneficiary or the beneficiary's authorized representative initiates additional contact with or by the plan, all other marketing and outreach activities in the beneficiary's room must follow the requirements for beneficiary contact under § 422.2264

(5) All other activities with healthcare providers or in the healthcare setting must comply with §§ 422.2266(a), (b), (c), (d), and (e).

[86 FR 6108, Jan. 19, 2021]

§ 422.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as required.

(a) *Standards for required materials and content.* All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font, Times New Roman or equivalent.

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Specifically, MA organizations must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (4) of this section or accessible format upon receiving a request for the materials in a non-English language or accessible format or when otherwise learning of the enrollee's primary language or need for an accessible format. This requirement also applies to the individualized plans of care described in § 422.101(f)(1)(ii) for special needs plan enrollees.

(4) For any fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan, as defined at § 422.2, or applicable integrated plan, as defined at § 422.561, be translated into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation

standard in paragraph (a)(2) of this section.

(5) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials.* Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, an MA organization must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing Part D language for a MA-only plan).

(vi) Adding the SMID.

(vii) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(2) The MA organization may develop accompanying language for standardized material or content, provided that language does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification and MA organizations may draft a letter that includes the standardized content in the body of the letter; the remaining language in the letter is at the plan's discretion, provided it does not conflict with the standardized content or other regulatory standards.

(c) *Model materials.* Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, MA organizations:

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the MA organization is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials.* MA organizations must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the MA organization has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the MA organization may mail one copy to the household. The MA organization must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization from the enrollee, MA organizations may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: the Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The MA organization may mail one notice for all materials or multiple notices.

(B) Notices for prospective year materials may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified materials by October 15 of each year.

(C) The MA organization may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the materials, the date the materials will be available if not currently available, and a phone number to request that hard-copy materials be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be material specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days of the request.

(ii) With prior authorization from the enrollee, MA organizations may provide any required material or content electronically. To do so, MA organizations must:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within three business days of the request.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content.* The following are required materials that must be provided to current and prospective enrollees, as applicable, in the form and manner outlined in this section. Unless otherwise noted or instructed by CMS and subject to §422.2263(a) of this chapter, required materials may be sent once a fully executed contract is in place, but no later than the due dates listed for each material in this section.

(1) *Evidence of Coverage (EOC).* The EOC is a standardized communications material through which certain required information (under §422.111(b)) must be provided annually and must be provided:

(i) To current enrollees of the plan by October 15, prior to the year to which the EOC applies.

(ii) To new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Part C explanation of benefits (EOB).* The EOB is a model communications material through which plans must provide the information required under §422.111(k). MA organizations may send this monthly or per claim with a quarterly summary.

(3) *Annual notice of change (ANOC).* The ANOC is a standardized marketing material through which plans must provide the information required under §422.111(d)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, or December 1 effective date must receive within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(4) *Pre-Enrollment checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. For telephonic enrollments, the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. It references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(viii) Effect on current coverage.

(5) *Summary of Benefits (SB).* MA organizations must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective enrollees, known as the SB. The SB is a model marketing material. It must be in a clear and accurate form.

(i) The SB must be provided with an enrollment form as follows:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where the SB can be accessed.

(ii) The SB must include the following information:

(A) Information on the following medical benefits, starting in the top half of the first page and in the order as identified in paragraphs (A)(1) through (A)(10), including—

(*1*) Monthly Plan Premium.

(*2*) Deductible/Out-of-pocket limits.

(*3*) Inpatient/Outpatient Hospital coverage.

(*4*) Ambulatory Surgical Center (ASC).

(*5*) Doctor Visits (Primary Care Providers and Specialists).

(*6*) Preventive Care.

(*7*) Emergency Care/Urgently Needed Services.

(*8*) Diagnostic Services/Labs/Imaging.

(*9*) Hearing Services/Dental Services/Vision Services.

(*10*) Mental Health Services.

(B) Information on prescription drug expenses, including:

(*1*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*2*) A statement that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30-or 90-day supply), when applicable.

(C) For Medicare Medical Savings Account Plans (MSAs), the SB must include the following:

(*1*) The amount Medicare deposits into the beneficiaries MSA account.

(*2*) A statement that the beneficiary pays nothing once the deductible is met.

(D) For dual eligible special needs plan (D–SNP)s, the SB must identify or describe the Medicaid benefits to prospective enrollees. This may be done by either of the following:

(*1*) Including the Medicaid benefits in the SB.

(*2*) Providing a separate document identifying the Medicaid benefits that accompanies the SB.

(E) For D–SNPs open to dually eligible enrollees with differing levels of cost, the SB must:

(*1*) State how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(*2*) Describe the Medicaid benefits, if any, provided by the plan.

(F) Fully integrated dual eligible SNPs (FIDE SNPs) and highly integrated D–SNPs, as defined in § 422.2, that provide Medicaid benefits have the option to display integrated Medicare and Medicaid benefits in the SB.

(G) MA organizations may describe or identify other health related benefits in the SB.

(6) *Enrollment/Election form.* This is a model communications material through which plans must provide the information required under § 422.60(c).

(7) *Enrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.60(e)(3).

(8) *Disenrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.74(b).

(9) *Mid-Year Change Notification.* This is a model communications material through which plans must provide a notice to enrollees when there is a mid-year change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in this part, must be provided 30 days in advance.

(ii) For National Coverage Determination (NCD) changes announced or finalized less than 30 days before their effective date, a notification is required as soon as possible.

(iii) Mid-year NCD or legislative changes must be provided no later than 30 days after the NCD is announced or the legislative change is effective.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(10) *Non-renewal Notice.* This is a standardized communications material through which plans must provide the information required under § 422.506.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in

special needs plans (SNPs). Information about non-renewals or service area reductions may not be released to the public, including the Non-renewal Notice, until CMS provides notification to the plan.

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that the plan will no longer be offered and the date the plan will end.

(B) Provide information about any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period), including the last day the enrollee has to make a Medicare health plan selection.

(C) Explain what the enrollee must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) As required under §422.506(a)(2)(ii)(A), provide a CMS-approved written description of alternative MA plan, MA–PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiary's' region in the enrollee's notice.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1–800–MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(G) Explain Medigap to applicable enrollees and the special right to buy a Medigap policy, and include a Medigap fact sheet with the non-renewal notice that explains Medigap coverage, policy, options to compare Medigap policies, and options to buy a Medigap policy.

(H) Include the MA organization's call center telephone number, TTY number, and hours and days of operation.

(11) *Provider Directory*. This is a model communications material through which plans must provide the information under §422.111(b)(3). The Provider Directory must:

(i) Be provided to current enrollees of the plan by October 15 of the year prior to the applicable year.

(ii) Be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Be provided to current enrollees upon request, within three business days of the request.

(iv) Be updated any time the MA organization becomes aware of changes.

(A) Updates to the online provider directories must be completed within 30 days of receiving information requiring update.

(B)(*1*) Updates to hardcopy provider directories must be completed within 30 days.

(*2*) Hard copy directories that include separate updates via addenda are considered up-to-date.

(12) *Provider Termination Notice*. This is a model communications material through which plans must provide the information required under §422.111(e).

(i) The written Provider Termination Notice must be provided in hard copy via U.S. mail (first class postage is recommended, but not required).

(ii) The written Provider Termination Notice must do all of the following:

(A) Inform the enrollee that the provider will no longer be in the network and the date the provider will leave the network.

(B) Include names and phone numbers of in-network providers that the enrollee may access for continued care (this information may be supplemented with information for accessing a current provider directory, including both online and direct mail options).

(C) Explain how the enrollee may request a continuation of ongoing medical treatment or therapies with their current provider.

(D) Provide information about the annual coordinated election period and the MA open enrollment period, as well as explain that an enrollee who is impacted by the provider termination may contact 1–800–MEDICARE to request assistance in identifying and switching to other coverage, or to request consideration for a special election period, as specified in §422.62(b)(26), based on the individual's unique circumstances and consistent with existing parameters for this SEP.

(E) Include the MA organization's call center telephone number, TTY

number, and hours and days of operation.

(iii) The telephonic Provider Termination Notice specified in § 422.111(e)(1)(i) must relay the same information as the written Provider Termination Notice as described in paragraph (e)(12)(ii) of this section.

(13) *Star Ratings Document.* This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form, as follows:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New MA organizations that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(14) *Organization Determination Notice.* This is a model communications material through which plans must provide the information under § 422.568.

(15) *Excluded Provider Notice.* This is a model communications material through which plans must notify enrollees when a provider they visit or consult has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(16) *Notice of Denial of Medical Coverage or Payment (NDMCP) (also known as the Integrated Denial Notice (IDN)).* This is a standardized communications material used to convey beneficiary appeal rights when a plan has denied a service as non-covered or excluded from benefits.

(17) *Notice of Medicare Non-Coverage (NOMNC).* This is a standardized communications material used to convey beneficiary appeal rights when a plan is terminating previously-approved coverage in a Skilled Nursing Facility (SNF), Comprehensive Outpatient Rehabilitation Facility (CORF), or Home Health setting (HHA).

(18) *Detailed Explanation of Non-Coverage (DENC).* This is a standardized communications material used to convey to a beneficiary why their current Medicare covered SNF, CORF or HHA services should end.

(19) *Appointment of Representative (AOR).* This is a standardized communications material used to authorize or appoint an individual to act on behalf of a beneficiary for the purpose of a specific appeal, grievance, or organization determination.

(20) *An Important Message From Medicare About Your Rights (IM).* This is a standardized communications material used to convey a beneficiary's rights as a hospital inpatient and appeal rights when their covered inpatient hospital stay is ending.

(21) *Detailed Notice of Discharge Form (DND).* This is a standardized communications material, as required under § 422.622(e), used to convey to a beneficiary why their current Medicare covered inpatient hospital stay should end.

(22) *Medicare Outpatient Observation Notice (MOON).* This is a standardized communications material used to inform a beneficiary that he or she is an outpatient receiving observation services.

(23) *Appeal and Grievance Data Form.* This is a standardized communications material used to convey organization-specific grievance and appeals data.

(24) *Request for Administrative Law Judge (ALJ) Hearing.* This is a standardized communications material used to formally request a reconsideration of the independent review entity's determination.

(25) *Attorney Adjudicator Review in Lieu of ALJ Hearing.* This is a standardized communications material used to request that an attorney adjudicator review a previously determined decision rather than having an ALJ do so.

(26) *Notice of Right to an Expedited Grievance*. This is a model communications material used to convey a Medicare enrollee's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(27) *Waiver of Liability Statement*. This is a model communications material used by non-contracted providers to waive beneficiary liability for payment for denied services while utilizing the enrollee appeals process under subpart M of part 422.

(28) *Notice of Appeal Status*. This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(29) *Notice of Dismissal of Appeal*. This is a model communications material used to convey the rationale by an MA organization to dismiss beneficiary's appeal.

(30) *Member ID card*. The member ID card is a model communications material that plans must provide to enrollees as required under §422.111(i). The member ID card—

(i) Must be provided to new enrollees within ten calendars days from receipt of CMS confirmation of enrollment or by the last day of the month prior to the plan effective date, whichever is later;

(ii) Must include the plan's—

(A) Website address;

(B) Customer service number (the member ID card is excluded from the hours of operations requirement under §422.2262(c)(1)(i)); and

(C) Contract/PBP number;

(iii) Must include, if issued for a PPO and PFFS plan, the phrase ''Medicare limiting charges apply.'';

(iv) May not use a member's Social Security number (SSN), in whole or in part;

(v) Must be updated whenever information on a member's existing card changes; in such cases an updated card must be provided to the member;

(vi) Is excluded from the translation requirement under paragraphs (a)(2) through (4) of this section; and

(vii) Is excluded from the 12-point font size requirement under paragraph (a)(1) of this section.

(31) *Multi-language insert (MLI)*. This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(i) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5-percent service area threshold, where it determines that this inclusion would be appropriate.

(ii) The MLI must be provided with all required materials under paragraph (e) of this section.

(iii) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(iv) When used as a standalone material, the MLI may include organization name and logo.

(v) When mailing multiple required materials together, only one MLI is required.

(vi) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(32) *Federal Contracting Statement*. This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example, HMO, HMO SNP, PPO, PFFS, PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, MA organizations may incorporate a statement that the organization has a contract with the state/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) MA organizations must include the Federal Contracting Statement on all marketing materials with the exception of the following:

(A) Banners and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(E) Envelopes.

(33) *Star Ratings Disclaimer*. This is model content through which plans must:

(i) Convey that MA organizations are evaluated yearly by Medicare.

(ii) Convey that the ratings are based on a 5-star rating system.

(iii) Include the model content in disclaimer form or within the material whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a giveaway items such as a pens or rulers).

(34) *SSBCI Disclaimer*. This is model content through which MA organizations must:

(i) Convey the benefits mentioned are a part of special supplemental benefits.

(ii) Convey that not all members will qualify.

(iii) Include the model content in the material copy which mentions SSBCI benefits.

(35) *Accommodations Disclaimer*. This is model content through which MA organizations must:

(i) Convey that accommodations for persons with special needs are available.

(ii) Provide a telephone number and TTY number.

(iii) Include the model content in disclaimer form or within the body of the material on any advertisement of invitation to all events described under § 422.2264(c).

(36) *Mailing Statements*. This is standardized content. It consists of statements on envelopes that MA organizations must include when mailing information to current members, as follows:

(i) MA organizations must include the following statement when mailing information about the enrollee's current plan: ''Important [Insert Plan Name] information.''

(ii) MA organizations must include the following statement when mailing health and wellness information: ''Health and wellness or prevention information.''

(iii) The MA organization must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple MA organizations must also comply with this requirement; however, they do not have to include a plan name.

(37) *Promotional Give-Away Disclaimer*. This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(38) *Provider Co-branded Material Disclaimer*. This is model content through which MA organizations must:

(i) Convey, as applicable, that other pharmacies, physicians or providers are available in the plan's network.

(ii) Include the model content in disclaimer form or within the material whenever co-branding relationships with network provider are mentioned, unless the co-branding is with a provider network or health system that represents 90 percent or more of the network as a whole.

(39) *Out of Network Non-Contracted Provider Disclaimer*. This is standardized content. The disclaimer consists of the statement: ''Out-of-network/non-contracted providers are under no obligation to treat Plan members, except in emergency situations. Please call our customer service number or see your Evidence of Coverage for more information, including the cost-sharing that applies to out-of-network services,'' and must be included whenever materials reference out-of-network/non-contracted providers.

(40) *NCQA SNP Approval Statement*. This is model content and must be used by SNPs who have received NCQA approval. MA organizations must:

(i) Convey that MA organization has been approved by the National Committee for Quality Assurance (NCQA) to operate as a Special Needs Plan (SNP).

(ii) Include the last contract year of NCQA approval.

(iii) Convey that the approval is based on a review of [insert Plan Name's] Model of Care.

(iv) Not include numeric SNP approval scores.

(41) *Third-party marketing organization disclaimer*. This is standardized content. If a TPMO does not sell for all MA organizations in the service area the disclaimer consists of the statement: ''We do not offer every plan available in your area. Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. Please contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program to get information on all of your options.'' If the TPMO sells for all MA organizations in the service area the disclaimer consists of the statement: ''Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. You can always contact *Medicare.gov*, 1–800–MEDICARE, or your local State Health Insurance Program for help with plan choices.'' The MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

[86 FR 6108, Jan. 19, 2021, as amended at 87 FR 27898, May 9, 2022; 88 FR 22336, Apr. 12, 2023; 88 FR 34780, May 31, 2023]

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

In its marketing, the MA organization must:

(a) Demonstrate to CMS' satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) 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.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the organization has informed that State it has appointed, consistent with the appointment process provided for under State law.

(d) Report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

(e) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

[73 FR 54220, Sept. 18, 2008, as amended at 73 FR 54250, Sept. 18, 2008; 76 FR 21569, Apr. 15, 2011; 83 FR 16735, Apr. 16, 2018; 88 FR 22337, Apr. 12, 2023]

§ 422.2274 Agent, broker, and other third-party requirements.

If an MA organization uses agents and brokers to sell its Medicare plans, the requirements in paragraphs (a) through (e) of this section are applicable. If an MA organization makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

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

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a plan or product offered by an MA organization including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(ii) Does not include any of the following:

(A) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(B) Reimbursement for mileage to, and from, appointments with beneficiaries.

(C) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into an MA plan. Beginning January 1, 2021, the national FMV is $539, the FMV for Connecticut, Pennsylvania, and the District of Columbia is $607, the FMV for California and New Jersey is $672, and the FMV for Puerto Rico and the U.S. Virgin Islands is $370. For subsequent years, FMV is calculated by adding the current year FMV and the product of the current year FMV and MA Growth Percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued pursuant to § 422.312.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan versus subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA–PD replaced with another MA or MA–PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or, MA–PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA–PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA–PD plan or PDP.

(b) *Agent/broker requirements.* Agents and brokers who represent MA organizations must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *MA organization oversight.* MA organizations must oversee first tier, downstream, and related entities that represent the MA organization to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements. MA organizations must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) of health insurance in that State, and whom the MA organization has informed that State it has appointed, consistent with the appointment process for agents and brokers provided for under State law.

(2) As required under applicable State law, report the termination of an agent or broker to the State and the reason for termination.

(3) Report to CMS all enrollments made by unlicensed agents or brokers and for-cause terminations of agents or brokers.

(4) On an annual basis, provide training and testing to agents and brokers on Medicare rules and regulations, the plan products that agents and brokers will sell, including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis by the last Friday in July, report to CMS whether the

MA organization intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent or broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure beneficiaries are not charged marketing consulting fees when considering enrollment in MA plans.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as to Medicare beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(12) Ensure that, prior to an enrollment, CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics include information regarding primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network), regarding pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network), prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered), costs of health care services, premiums, benefits, and specific health care needs.

(d) *Compensation requirements.* MA organizations must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agents and brokers.

(1) *General rules.* (i) MA organizations may only pay agents or brokers who meet the requirements in paragraph (b) of this section.

(ii) MA organizations may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section.

(iii) MA organizations may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) MA organizations may only pay compensation for the number of months a member is enrolled.

(2) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year, MA organizations may pay compensation at or below FMV.

(i) MA organizations may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) MA organizations must pay prorated initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an ''unlike plan type'' change. In that case, the new plan would only pay the

months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year, MA plans may pay compensation at an amount up to 50 percent of FMV.

(i) MA plans may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new ''like plan type''.

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in an MA–PD, MA organizations may pay only the MA compensation (and not compensation for Part D enrollment under § 423.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP plan, the MA plan sponsor may pay for the MA plan enrollment and the Part D plan may pay for the PDP plan enrollment.

(iv) When a beneficiary changes from two plans (for example, a MA plan and a stand-alone PDP) (dual enrollments) to one plan (MA–PD), the MA organization may only pay compensation at the renewal rate for the MA–PD product.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).* (i) MA organizations must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. MA organizations may choose to recoup or pay compensation for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due) during the same year.

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first three months of enrollment (known as rapid disenrollment), except as provided in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the Medicare program, including for the following reasons:

(*1*) Other creditable coverage (for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent or broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent or broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation. Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments other than compensation (administrative payments).* (1) Payments made for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Administrative payments can be based on enrollment provided payments are at or below the value of those services in the marketplace.

(f) *Payments for referrals.* Payments may be made to individuals for the referral (including a recommendation, provision, or other means of referring beneficiaries) to an agent, broker or other entity for potential enrollment into a plan. The payment may not exceed $100 for a referral into an MA or MA–PD plan and $25 for a referral into a PDP plan.

(g) *TPMO oversight.* In addition to any applicable FDR requirements under § 422.504(i), when doing business with a TPMO, either directly or indirectly through a downstream entity, MA plans must implement the following as a part of their oversight of TPMOs:

(1) When a TPMO is not otherwise an FDR, the MA organization is responsible for ensuring that the TPMO adheres to any requirements that apply to the MA plan.

(2) Contracts, written arrangements, and agreements between the TPMO and an MA plan, or between the TPMO and an MA plan's FDR, must ensure the TPMO:

(i) Discloses to the MA organization any subcontracted relationships used for marketing, lead generation, and enrollment.

(ii) Record all marketing, sales, and enrollment calls, including the audio portion of calls via web-based technology, in their entirety.

(iii) Reports to plans monthly any staff disciplinary actions or violations of any requirements that apply to the MA plan associated with beneficiary interaction to the plan.

(iv) Uses the TPMO disclaimer as required under § 422.2267(e)(41).

(3) Ensure that the TPMO, when conducting lead generating activities, either directly or indirectly for an MA organization, must, when applicable:

(i) Disclose to the beneficiary that his or her information will be provided to a licensed agent for future contact. This disclosure must be provided as follows:

(A) Verbally when communicating with a beneficiary through telephone.

(B) In writing when communicating with a beneficiary through mail or other paper.

(C) Electronically when communicating with a beneficiary through email, online chat, or other electronic messaging platform.

(ii) Disclose to the beneficiary that he or she is being transferred to a licensed agent who can enroll him or her into a new plan.

[86 FR 6112, Jan. 19, 2021, as amended at 87 FR 27899, May 9, 2022; 88 FR 22337, Apr. 12, 2023]

§ 422.2276 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. These materials are not subject to CMS prior review and approval.

Subpart W [Reserved]

Subpart X—Requirements for a Minimum Medical Loss Ratio

SOURCE: 78 FR 31307, May 23, 2013, unless otherwise noted.

§ 422.2400 Basis and scope.

This subpart is based on sections 1857(e)(4), 1860D–12(b)(3)(D), and 1106 of the Act, and sets forth medical loss

ratio requirements for Medicare Advantage organizations, financial penalties and sanctions against MA organizations when minimum medical loss ratios are not achieved by MA organizations, and release of medical loss ratio data to entities outside of CMS.

[81 FR 80557, Nov. 15, 2016]

§ 422.2401 Definitions.

Non-claims costs means those expenses for administrative services that are not—

(1) Incurred claims (as provided in § 422.2420(b)(2) through (4));

(2) Expenditures on quality improving activities (as provided in § 422.2430);

(3) Licensing and regulatory fees (as provided in § 422.2420(c)(2)(i));

(4) State and Federal taxes and assessments (as provided in § 422.2420(c)(2)(ii) and (iii)).

[78 FR 31307, May 23, 2013; 78 FR 43821, July 22, 2013]

§ 422.2410 General requirements.

(a) For contracts beginning in 2014 or later, an MA organization (defined at § 422.2) is required to report the information required under § 422.2460 for each contract under this part for each contract year.

(b) *MLR requirement.* If CMS determines for a contract year that an MA organization has an MLR for a contract that is less than 0.85, the MA organization has not met the MLR requirement and must remit to CMS an amount equal to the product of the following:

(1) The total revenue of the MA contract for the contract year.

(2) The difference between 0.85 and the MLR for the contract year.

(c) If CMS determines that an MA organization has an MLR for a contract that is less than 0.85 for 3 or more consecutive contract years, CMS does not permit the enrollment of new enrollees under the contract for coverage during the second succeeding contract year.

(d) If CMS determines that an MA organization has an MLR for a contract that is less than 0.85 for 5 consecutive contract years, CMS terminates the contract per § 422.510(b)(1) and (d) effective as of the second succeeding contract year.

[78 FR 31307, May 23, 2013, as amended at 83 FR 16736, Apr. 16, 2018]

§ 422.2420 Calculation of the medical loss ratio.

(a) *Determination of MLR.* (1) The MLR for each contract under this part is the ratio of the numerator (as defined in paragraph (b) of this section) to the denominator (as defined in paragraph (c) of this section). An MLR may be increased by a credibility adjustment according to the rules at § 422.2440, or subject to an adjustment determined by CMS to be warranted based on exceptional circumstances for areas outside the 50 states and the District of Columbia.

(2) The MLR for an MA contract—

(i) Not offering Medicare prescription drug benefits must only reflect costs and revenues related to the benefits defined at § 422.100(c); and

(ii) That includes MA–PD plans (defined at § 422.2) must also reflect costs and revenues for benefits described at § 423.104(d) through (f) of this chapter.

(b) Determining the *MLR numerator.* (1) For a contract year, the numerator of the MLR for an MA contract (other than an MSA contract) must equal the sum of paragraphs (b)(1)(i) through (iii) of this section, and the numerator of the MLR for an MSA contract must equal the sum of paragraphs (b)(1)(i), (iii), and (iv) of this section. The numerator must be determined in accordance with paragraphs (b)(5) and (6) of this section.

(i) Incurred claims for all enrollees, as defined in paragraphs (b)(2) through (4) of this section.

(ii) The amount of the reduction, if any, in the Part B premium for all MA plan enrollees under the contract for the contract year.

(iii) The expenditures under the contract for activities that improve health care quality, as defined in § 422.2430.

(iv) The amount of the annual deposit into the medical savings account described at § 422.4(a)(2).

(2) *Incurred claims for clinical services and prescription drug costs.* Incurred claims must include the following:

(i) Amounts that the MA organization pays (including under capitation

contracts) for covered services, described at paragraph (a)(2) of this section, provided to all enrollees under the contract.

(ii) For an MA contract that includes MA–PD plans (described in paragraph (a)(2) of this section), drug costs provided to all enrollees under the contract, as defined at § 423.2420(b)(2)(i) of this chapter.

(iii) Unpaid claims reserves for the current contract year, including claims reported in the process of adjustment.

(iv) Percentage withholds from payments made to contracted providers.

(v) Incurred but not reported claims based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(vi) Changes in other claims-related reserves.

(vii) Claims that are recoverable for anticipated coordination of benefits.

(viii) Claims payments recoveries received as a result of subrogation.

(ix) [Reserved]

(x) Reserves for contingent benefits and the medical claim portion of lawsuits.

(xi) The amount of incentive and bonus payments made to providers.

(3) Adjustments that must be deducted from incurred claims include the following:

(i) Overpayment recoveries received from providers.

(4) *Exclusions from incurred claims.* The following amounts must not be included in incurred claims:

(i) Non-claims costs, as defined in § 422.2401, which include the following:

(A) Amounts paid to third party vendors for secondary network savings.

(B) Amounts paid to third party vendors for any of the following:

(*1*) Network development.

(*2*) Administrative fees.

(*3*) Claims processing.

(*4*) Utilization management.

(C) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee, such as the following:

(*1*) Medical record copying costs.

(*2*) Attorneys' fees.

(*3*) Subrogation vendor fees.

(*4*) Bona fide service fees.

(*5*) Compensation to any of the following:

(*i*) Paraprofessionals.

(*ii*) Janitors.

(*iii*) Quality assurance analysts.

(*iv*) Administrative supervisors.

(*v*) Secretaries to medical personnel.

(*vi*) Medical record clerks.

(ii) Amounts paid to CMS as a remittance under § 422.2410(b).

(5) Incurred claims under this part for policies issued by one MA organization and later assumed by another entity must be reported by the assuming organizations for the entire MLR reporting year during which the policies were assumed and no incurred claims under this part for that contract year must be reported by the ceding MA organization.

(6) Reinsured incurred claims for a block of business that was subject to indemnity reinsurance and administrative agreements effective before March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(c) *Determining the MLR denominator.* For a contract year, the denominator of the MLR for an MA contract must equal the total revenue under the contract. Total revenue under the contract is as described in paragraph (c)(1) of this section, net of deductions described in paragraph (c)(2) of this section, taking into account the exclusions described in paragraph (c)(3) of this section, and n accordance with paragraphs (c)(4) and (c)(5) of this section.

(1) CMS' payments to the MA organization for all enrollees under a contract, reported on a direct basis, including the following:

(i) Payments under § 422.304(a)(1) through (3) and (c).

(ii) The amount applied to reduce the Part B premium, as provided under § 422.266(b)(3).

(iii) Payments under § 422.304(b)(1), as reconciled per § 423.329(c)(2)(ii) of this chapter.

(iv) All premiums paid by or on behalf of enrollees to the MA organization as a condition of receiving coverage under an MA plan, including CMS' payments for low income premium subsidies under §422.304(b)(2).

(v) All unpaid premium amounts that an MA organization could have collected from enrollees in the MA plan(s) under the contract.

(vi) All changes in unearned premium reserves.

(vii) Payments under §423.315(e) of this chapter.

(2) The following amounts must be deducted from total revenue in calculating the MLR:

(i) *Licensing and regulatory fees.* (A) Statutory assessments to defray the operating expenses of any State or Federal department, such as the ''user fee'' described in section 1857(e)(2) of the Act.

(B) Examination fees in lieu of premium taxes as specified by State law.

(ii) *Federal taxes and assessments.* All Federal taxes and assessments allocated to health insurance coverage.

(iii) *State taxes and assessments.* State taxes and assessments such as the following:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly.

(B) Guaranty fund assessments.

(C) Assessments of State industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(D) State income, excise, and business taxes other than premium taxes.

(iv) *Community benefit expenditures.* Community benefit expenditures are payments made by a Federal income tax-exempt MA organization for community benefit expenditures as defined in paragraph (c)(2)(iv)(A) of this section, limited to the amount defined in paragraph (c)(2)(iv)(B) of this section, and allocated to a contract as required under paragraph (d)(1) of this section.

(A) Community benefit expenditures means expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden.

(B) Such payment may be deducted up to the limit of either 3 percent of total revenue under this part or the highest premium tax rate in the State for which the Part D sponsor is licensed, multiplied by the Part D sponsor's earned premium for the contract.

(3) The following amounts must not be included in total revenue:

(i) The amount of unpaid premiums for which the MA organization can demonstrate to CMS that it made a reasonable effort to collect.

(ii) The following EHR payments and adjustments:

(A) EHR incentive payments for meaningful use of certified electronic health records by qualifying MAOs, MA EPs and MA-affiliated eligible hospitals that are administered under 42 CFR part 495 subpart C.

(B) EHR payment adjustments for a failure to meet meaningful use requirements that are administered under 42 CFR part 495 subpart C.

(iii) Coverage Gap Discount Program payments under §423.2320 of this chapter.

(4) Total revenue (as defined at §422.2420(c)) for policies issued by one MA organization and later assumed by another entity must be reported by the assuming entity for the entire MLR reporting year during which the policies were assumed and no revenue under this part for that contract year must be reported by the ceding MA organization.

(5) Total revenue (as defined at §422.2420(c)) that is reinsured for a block of business that was subject to indemnity reinsurance and administrative agreements effective prior to March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(d) *Allocation of expense*—(1) *General requirements.* (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of or criteria for one type of expense and the remainder fits into a different type of expense,

in which case the expense must be prorated between types of expenses.

(ii) Expenditures that benefit multiple contracts, or contracts other than those being reported, including but not limited to those that are for or benefit self-funded plans, must be reported on a pro rata share.

(2) *Description of the methods used to allocate expenses.* (i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories in paragraph (b) or (c) of this section will generally be the most accurate method.

(ii) Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the contracts incurring the expense.

(iii)(A) Any basis adopted to apportion expenses must be that which is expected to yield the most accurate results and may result from special studies of employee activities, salary ratios, premium ratios or similar analyses.

(B) Expenses that relate solely to the operations of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to other entities within a group.

[78 FR 31307, May 23, 2013; 78 FR 43821, July 22, 2013; 83 FR 16736, Apr. 16, 2018; 85 FR 33908, June 2, 2020]

§ 422.2430 Activities that improve health care quality.

(a) *Activity requirements.* (1) Activities conducted by an MA organization to improve quality must either—

(i) Fall into one of the categories in paragraph (a)(2) of this section and meet all of the requirements in paragraph (a)(3) of this section; or

(ii) Be listed in paragraph (a)(4) of this section.

(2) *Categories of quality improving activities.* The activity must be designed to achieve one or more of the following:

(i) To improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage.

(ii) To prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post-discharge reinforcement by an appropriate health care professional.

(iii) To improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology under the plan or coverage.

(iv) To promote health and wellness.

(v) To enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology. Such activities, such as Health Information Technology (HIT) expenses, are required to accomplish the activities that improve health care quality and that are designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, and are consistent with meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improving activities or make new quality improvement initiatives possible.

(3) The activity must be designed for all of the following:

(i) To improve health quality.

(ii) To increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.

(iii) To be directed toward individual enrollees or incurred for the benefit of

specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees.

(iv) To be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.

(4)(i) For an MA contract that includes MA–PD plans (described in § 422.2420(a)(2)), Medication Therapy Management Programs meeting the requirements of § 423.153(d) of this chapter.

(ii) Fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

(b) *Exclusions.* Expenditures and activities that must not be included in quality improving activities include, but are not limited to, the following:

(1) Those that are designed primarily to control or contain costs other than those that are related to fraud reduction.

(2) The pro rata share of expenses that are for lines of business or products other than those being reported, including but not limited to, those that are for or benefit self-funded plans.

(3) Those which otherwise meet the definitions for quality improving activities but which were paid for with grant money or other funding separate from premium revenue.

(4) Those activities that can be billed or allocated by a provider for care delivery and that are reimbursed as clinical services.

(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities (and that are not related to fraud reduction activities under paragraph (a)(4)(ii) of this section) or to meet regulatory requirements for processing claims, including ICD–10 implementation costs in excess of 0.3 percent of total revenue under this part, and maintenance of ICD–10 code sets adopted in accordance with to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended.

(6) That portion of the activities of health care professional hotlines that does not meet the definition of activities that improve health quality.

(7) All retrospective and concurrent utilization review.

(8) [Reserved]

(9) The cost of developing and executing provider contracts and fees associated with establishing or managing a provider network, including fees paid to a vendor for the same reason.

(10) Provider credentialing.

(11) Marketing expenses.

(12) Costs associated with calculating and administering individual enrollee or employee incentives.

(13) That portion of prospective utilization review that does not meet the definition of activities that improve health quality.

(14) Any function or activity not expressly permitted by CMS under this part.

[78 FR 31307, May 23, 2013, as amended at 83 FR 16736, Apr. 16, 2018]

§ 422.2440 Credibility adjustment.

(a) An MA organization may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) An MA organization may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 422.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 2,400 member months and fewer than or equal to 180,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 180,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 2,400 member months.

(e)(1) The credibility adjustment for a partially credible MA contract, other

than an MSA contract, is equal to the base credibility factor determined under paragraph (f) of this section.

(2) The credibility adjustment for a partially credible MA MSA contract is the product of the base credibility factor, as determined under paragraph (f) of this section, multiplied by the deductible factor, as determined under paragraph (g) of this section.

(f) The base credibility factor for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the base credibility factor. The base credibility factor for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

(g) The deductible factor is based on the enrollment-weighted average deductible for all MSA plans under the MA MSA contract, where the deductible for each plan under the contract is weighted by the plan's portion of the total number of member months for all plans under the contract. When the weighted average deductible exactly matches a deductible category listed in Table 2 of this section, the value associated with that deductible is the deductible factor. The deductible factor for a weighted average deductible between the values shown in Table 2 of section is determined by linear interpolation.

TABLE 1 TO § 422.2440—BASE CREDIBILITY FACTORS FOR MA CONTRACTS

Member months	Base credibility factor (additional percentage points)
<2,400	N/A (Non-credible).
2,400	8.4%.
6,000	5.3%.
12,000	3.7%.
24,000	2.6%.
60,000	1.7%.
120,000	1.2%.
180,000	1.0%.
>180,000	0.0% (Fully credible).

TABLE 2 TO § 422.2440—DEDUCTIBLE FACTORS FOR MA MSA CONTRACTS

Weighted average deductible	Deductible factor
<$2,500	1.000
$2,500	1.164
$5,000	1.402
≥$10,000	1.736

[85 FR 33908, June 2, 2020]

§ 422.2450 [Reserved]

§ 422.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the MA organization to calculate and verify the medical loss ratio (MLR) and remittance amount, if any, for each contract under this part, including the amount of incurred claims for original Medicare covered benefits, supplemental benefits, and prescription drugs; total revenue; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; and any remittance owed to CMS under § 422.2410.

(b) For contract years 2018 through 2022, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, the following information:

(1) *Fully credible and partially credible contracts.* For each contract under this part that has fully credible or partially credible experience, as determined in accordance with § 422.2440(d), the MA organization must report to CMS the MLR for the contract and the amount of any remittance owed to CMS under § 422.2410.

(2) *Non-credible contracts.* For each contract under this part that has non-credible experience, as determined in accordance with § 422.2440(d), the MA organization must report to CMS that the contract is non-credible.

(c) Total revenue included as part of the MLR calculation must be net of all projected reconciliations.

(d) Subject to paragraph (e) of this section, the MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

(e) With respect to an MA organization that has already submitted to CMS the MLR report or MLR data required under paragraph (a) or (b) of this section, respectively, for a contract for a contract year, paragraph (d) of this section does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, is regarded as the contract's MLR report or data submission for the contract year for purposes of this subpart.

[83 FR 16736, Apr. 16, 2018, as amended at 87 FR 27899, May 9, 2022]

§ 422.2470 Remittance to CMS if the applicable MLR requirement is not met.

(a) *General requirement.* For each contract year, an MA organization must provide a remittance to CMS if the contract's MLR does not meet the minimum MLR requirement required by § 422.2410(b) of this subpart.

(b) *Amount of remittance.* For each contract that does not meet the MLR requirement for a contract year, the MA organization must remit to CMS the amount by which the MLR requirement exceeds the contract's actual MLR multiplied by the total revenue of the contract, as provided in § 422.2420(c), for the contract year.

(c) *Timing of remittance.* CMS deducts the remittance from plan payments in a timely manner after the MLR is reported, on a schedule determined by CMS.

(d) *Treatment of remittance.* Payment to CMS must not be included in the numerator or denominator of any year's MLR.

§ 422.2480 MLR review and non-compliance.

To ensure the accuracy of MLR reporting, CMS conducts selected review of data submitted under § 422.2460 to determine that that the MLRs and remittance amounts under § 422.2410(b) and sanctions under § 422.2410(c) and (d), were accurately calculated, reported, and applied.

(a) The reviews include a validation of amounts included in both the numerator and denominator of the MLR calculation reported to CMS.

(b) MA organizations are required to maintain evidence of the amounts reported to CMS and to validate all data necessary to calculate MLRs.

(c)(1) Documents and records must be maintained for 10 years from the date such calculations were reported to CMS with respect to a given MLR reporting year.

(2) MA organizations must require any third party vendor supplying drug or medical cost contracting and claim adjudication services to the MA organization to provide all underlying data associated with MLR reporting to that MA organization in a timely manner, when requested by the MA organization, regardless of current contractual limitations, in order to validate the accuracy of MLR reporting.

(d) Data submitted under § 422.2460, calculations, or any other MLR submission required by this subpart found to be materially incorrect or fraudulent—

(1) Is noted by CMS;

(2) Appropriate remittance amounts are recouped by CMS; and

(3) Sanctions may be imposed by CMS as provided in § 422.752.

[78 FR 31307, May 23, 2013, as amended at 83 FR 16736, Apr. 16, 2018]

§ 422.2490 Release of Part C MLR data.

(a) *Terminology.* Subject to the exclusions in paragraph (b) of this section, Part C MLR data consists of the information submitted under § 422.2460.

(b) *Exclusions from Part C MLR data.* For the purpose of this section, the following items are excluded from Part C MLR data:

(1) Narrative descriptions that MA organizations submit to support the information reported to CMS pursuant to the reporting requirements at § 422.2460, such as descriptions of expense allocation methods.

(2)(i) Information that is reported at the plan level, such as the number of member months associated with each plan under a contract, including information submitted for a contract consisting of only one plan.

(ii) Amounts that are reported as expenditures for a specific type of supplemental benefit, where the entire

amount that is reported represents costs incurred by the only plan under the contract that offers that benefit.

(3) Any information that could be used to identify Medicare beneficiaries or other individuals.

(4) MLR review correspondence.

(5) Any information for a contract for those contract years for which the contract is determined to be non-credible, as defined in accordance with § 422.2440(d).

(c) *Data release.* CMS releases to the public Part C MLR data, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year.

[81 FR 80557, Nov. 15, 2016, as amended at 83 FR 16736, Apr. 16, 2018; 87 FR 27899, May 9, 2022]

Subpart Y [Reserved]

Subpart Z—Part C Recovery Audit Contractor Appeals Process

SOURCE: 79 FR 29961, May 23, 2014, unless otherwise noted.

§ 422.2600 Payment appeals.

If the Part C RAC did not apply its stated payment methodology correctly, an MA organization may appeal the findings of the applied methodology. The payment methodology itself is not subject to appeal.

§ 422.2605 Request for reconsideration.

(a) *Time for filing a request.* The request for reconsideration must be filed with the designated independent reviewer within 60 calendar days from the date of the demand letter received by the MA organization.

(b) *Content of request.* (1) The request for reconsideration must be in writing and specify the findings or issues with which the MA organization disagrees.

(2) The MA organization must include with its request all supporting documentary evidence it wishes the independent reviewer to consider.

(i) This material must be submitted in the format requested by CMS.

(ii) Documentation, evidence, or substantiation submitted after the filing of the reconsideration request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the MA organization's reconsideration request.

(1) The rebuttal must be submitted within 30 calendar days of the review entity's notification to CMS that it has received the MA organization's reconsideration request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the independent reviewer.

(d) *Review entity.* An independent reviewer conducts the reconsideration. The independent reviewer reviews the demand for repayment, the evidence and findings upon which it was based and any supporting documentation that the MA organization or CMS submitted in accordance with this section.

(e) *Notification of decision.* The independent reviewer informs the CMS and the MA organization of its decision in writing.

(f) *Effect of decision.* A reconsideration decision is final and binding unless the MA organization requests a hearing official review in accordance with § 422.2610.

(g) *Right to hearing official review.* An MA organization that is dissatisfied with the independent reviewer's reconsideration decision is entitled to a hearing official review as provided in § 422.2610.

§ 422.2610 Hearing official review.

(a) *Time for filing a request.* A MA organization must file with CMS a request for a hearing official review within 30 calendar days from the date of the independent reviewer's issuance of a reconsideration determination.

(b) *Content of the request.* (1) The request must be in writing and must specify the findings or issues in the reconsideration decision with which the MA organization disagrees and the reasons for the disagreements.

(2) The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(3) No new evidence may be submitted.

(4) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the MA organization's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the MA organization's submission of its hearing official review request.

(2) CMS sends its rebuttal to the MA organization at the same time it is submitted to the hearing official.

(d) *Conducting a review.* A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part C RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The MA organization submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the MA organization nor CMS may submit new evidence.

(e) *Hearing official decision.* The CMS hearing official decides the case within 60 days and sends a written decision to the MA organization and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with §422.2615.

§422.2615 Review by the Administrator.

(a) *Request for review by Administrator.* If an MA organization is dissatisfied with the hearing official's decision, it may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 30 calendar days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

(b) *Content of request.* The MA organization must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(1) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(2) Neither the MA organization, nor CMS may submit new evidence.

(c) *Discretionary review.* After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review.* The Administrator notifies the MA organization within 45 days of receiving the MA organization's hearing request of whether he or she intends to review the hearing official's decision.

(1) If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan that the request for review has been accepted. CMS sends its rebuttal statement to the plan at the same time it is submitted to the Administrator.

(2) If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *CMS Administrator's review.* If the CMS Administrator agrees to review the hearing official's decision, he or she determines, based upon this decision, the hearing record, and any arguments submitted by the MA organization or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The Administrator furnishes a written decision, which is final and binding, to the MA organization and to CMS.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

Subpart A—General Provisions

Sec.

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