

(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,