

(F) The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 422.2267(e), if provided by mail, is returned to the MA organization by the U.S. Postal Service as undeliverable and a forwarding address is not provided.

(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 within 10 calendar days of the plan's confirmation of the individual's residence outside of the plan service area or within the first 10 calendar days of the sixth month of an individual's temporary absence from the plan service area or, for individuals using a visitor/traveler benefit, within the first 10 calendar days of the last month of the allowable absence. If the plan learns of an individual's temporary absence from the plan service area after the expiration of the allowable period, the plan must send this notice within 10 calendar days of the plan learning of the absence.

(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) *Loss of special needs status.* If an enrollee loses special needs status and must be disenrolled under paragraph (b)(2)(iv) of this section, the SNP must provide the enrollee with a minimum of 30 days' advance notice of disenrollment, regardless of the date of loss of special needs status.

(i) The advance notice must be provided to the enrollee within 10 calendar days of the plan learning of the loss of special needs status and must afford the enrollee an opportunity to prove that they are still eligible to remain in the plan.

(ii) The advance notice must include all of the following:

(A) The disenrollment effective date.

(B) A description of eligibility for the SEP described in § 422.62(b)(11).

(C) If applicable all of the following:

(1) Information regarding the period of deemed continued eligibility authorized by § 422.52(d).

(2) The duration of the period of deemed continued eligibility.

(3) The consequences of not regaining special needs status within the period of deemed continued eligibility.

(iii) A final notice of involuntary disenrollment must be sent as follows:

(A) Within 3 business days following the disenrollment effective date, which is either—

(1) The last day of the period of deemed continued eligibility, if applicable; or

(2) A minimum of 30 days after providing the advance notice of disenrollment.

(B) Before submission of the disenrollment to CMS.

(iv) The final notice of involuntary disenrollment must include an explanation of the enrollee's right to file a grievance under the MA organization's grievance procedures that are required by § 422.564.

(9) *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.

(10) *Mid-year change in MSA eligibility.* If an individual is no longer eligible for an MA MSA plan due to a mid-year change in eligibility, disenrollment is effective the first day of the calendar month following the MA organization's notice to the individual that they are ineligible in accordance with § 422.74(b)(2)(vi) of this section.

(e) *Consequences of disenrollment—(1) Disenrollment for non-payment of premiums, disruptive behavior, fraud or abuse, loss of Part A or Part B or mid-year loss of MSA eligibility.* An individual who is disenrolled under paragraph (b)(1)(i) through (iii), (b)(2)(ii) or (b)(2)(vi) 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; 89 FR 30816, Apr. 23, 2024; 89 FR 63826, Aug. 6, 2024]

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 bene-

fits 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 dis-

tributed to beneficiaries for basic benefits.

(g) *Benefits affecting screening mammography, influenza vaccine, and pneumococcal 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(1)).

§ 422.100

42 CFR Ch. IV (10–1–24 Edition)

(1) 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 pro-

grams on the MA organization, evaluations of effectiveness of digital health literacy interventions, and demonstration of compliance with the requirements of this section.

(2) [Reserved]

(o) *Cost sharing standards for D-SNP PPOs.* Beginning on or after January 1, 2026, an MA organization offering a local PPO plan or regional PPO plan that is a dual eligible special needs plan must establish cost sharing for out-of-network services that—

(1) Complies with the limits described in paragraph (f)(6) of this section with the exception that references to the MOOP amounts refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans; and

(2) Complies with the limits described in paragraph (j)(1) of this section with the exception that references to the MOOP amounts refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans and, for regional PPO dual eligible special needs plans, excluding paragraph (j)(1)(i)(C)(2) and the last sentence of paragraph (j)(1)(i)(E) of this section.

[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; 89 FR 30817, Apr. 23, 2024]

§ 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 service 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 sta-

tus 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(1)) 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.

(vi) For I-SNPs, ensure that contracts with long-term care institutions (listed in the definition of the term institutionalized in §422.2) contain requirements allowing I-SNP clinical and care coordination staff access to enrollees of the I-SNP who are institutionalized.

(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 each MOC must meet an aggregate minimum benchmark of 70 percent, and a plan's model of care is only approved if each element of the model of care meets the minimum benchmark and the model of care meets the aggregate minimum benchmark.

(A) An MOC for a C-SNP that receives a passing score is approved for 1 year.

(B)(1) An MOC for an I-SNP or D-SNP that receives an aggregate minimum benchmark score of 85 percent or greater is approved for 3 years.

(2) An MOC for an I-SNP or D-SNP that receives a score of 75 percent to 84 percent is approved for 2 years.

(3) An MOC for an I-SNP or DSNP that receives a score of 70 percent to 74 percent is approved for 1 year.

(C) For an MOC that fails to meet a minimum element benchmark score of 50 percent or an MOC that fails to meet the aggregate minimum benchmark of 70 percent, the MA organization is permitted a one-time opportunity to re-submit the corrected MOC for reevaluation; and an MOC that is corrected

and resubmitted using this cure period is approved for only 1 year.

(iv) An MA organization sponsoring a SNP that seeks to revise the MOC before the end of the MOC approval period may submit changes to the MOC as off-cycle MOC submissions for review by NCQA as follows:

(A) C-SNPs, D-SNPs and I-SNPs must submit updates and corrections to their NCQA-approved MOC when CMS requires an off-cycle submission to ensure compliance with applicable law.

(B) D-SNPs and I-SNPs must submit updates and corrections to their NCQA approved MOC between June 1st and November 30th of each calendar year if the I-SNP or D-SNP wishes to make any of the following revisions:

(1) Substantial changes in policies or procedures pertinent to any of the following:

(i) The health risk assessment (HRA) process.

(ii) Revising processes to develop and update the Individualized Care Plan (ICP).

(iii) The integrated care team process.

(iv) Risk stratification methodology.

(v) Care transition protocols.

(2) Target population changes that warrant modifications to care management approaches.

(3) Changes in a SNP's plan benefit package between consecutive contract years that can considerably impact critical functions necessary to maintain member well-being and are related to SNP operations.

(4) Changes in level of authority or oversight for personnel conducting care coordination activities (for example, medical provider to non-medical provider, clinical vs. non-clinical personnel).

(5) Changes to quality metrics used to measure performance.

(C) NCQA only reviews off-cycle submissions after the start of the effective date of the current MOC unless CMS deems it necessary to ensure compliance with the applicable regulations.

(D) SNPs may not implement any changes to a MOC until NCQA has reviewed and approved the off-cycle MOC changes. NCQA does not rescure the MOC during the off-cycle review of

changes to the MOC, but changes are reviewed and determined by NCQA to be either "Acceptable" or "Non-acceptable." "Acceptable" means that the changes have been approved by NCQA and the MOC has been updated; "Non-acceptable" means the changes have been rejected by NCQA and the MOC has not been changed. If NCQA determines that off-cycle changes are unacceptable, the SNP must continue to implement the MOC as originally approved.

(E) Successful revision of the MOC under paragraph (f)(3)(iv)(B) of this section does not change the MOC's original period of approval.

(F) C-SNPs are only permitted to submit an off-cycle MOC submission when CMS requires an off-cycle submission to ensure compliance with applicable law.

(G) When a deficiency is identified in the off-cycle MOC revision(s) submitted by a SNP, the SNP has one opportunity to submit a corrected off-cycle revision between June 1st and November 30th of each calendar year.

[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; 89 FR 30817, Apr. 23, 2024; 89 FR 79451, Sept. 30, 2024]

§ 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 or 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) *MA organization responsibilities.* An MA organization that includes an item or service as SSBCI in its bid must be able to demonstrate through relevant acceptable evidence that the item or service has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. By the date on which an MA organization submits its bid, the MA organization must establish a written bibliography of relevant acceptable evidence concerning the impact that the item or service has on the health or overall function of its recipient. For each citation in the written bibliography, the MA organization must include a working hyperlink to or a document containing the entire source cited.

(i) Relevant acceptable evidence includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to investigate whether the item or service impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same.

(ii) An MA organization must include in its bibliography a comprehensive list of relevant acceptable evidence published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered, including any available negative evidence and literature.

(iii) If no evidence of the type described in paragraphs (f)(3)(i) and (ii) of this section exists for a given item or service, then MA organization may cite case studies, federal policies or reports, internal analyses, or any other investigation of the impact that the item or service has on the health or overall function of its recipient as relevant acceptable evidence in the MA organization's bibliography.

(iv) The MA organization must make its bibliography of relevant acceptable evidence available to CMS upon request.

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

(i) 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)(A) Have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI; and

(B) Document the written policies specified in paragraph (f)(4)(iii)(A) of this section and the objective criteria on which the written policies are based.

(iv) Document each eligibility determination for an enrollee, whether eligible or ineligible, to receive a specific SSBCI and make this information available to CMS upon request.

(v) Maintain without modification, as it relates to an SSBCI, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations for the full coverage year.

(5) *CMS review of SSBCI offerings in bids.* (i) CMS may decline to approve an MA organization's bid if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting.

(ii) CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, taking into account updates to the relevant acceptable evidence applicable to each item or service.

(iii) This provision does not limit CMS's authority to review and negotiate bids or to reject bids under section 1854(a) of the Act and 42 CFR part 422 subpart F nor does it limit CMS's authority to review plan benefits and

bids for compliance with all applicable requirements.

[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; 89 FR 30818, Apr. 23, 2024; 89 FR 63826, Aug. 6, 2024]

§ 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

§ 422.106

42 CFR Ch. IV (10–1–24 Edition)

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 en-

rollee 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

§ 422.110

42 CFR Ch. IV (10–1–24 Edition)

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:

(I) 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) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

(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 assess-

ment 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.

(1) *Mid-year notice of unused supplemental benefits.* Beginning January 1, 2026, MA organizations must send notification annually, no sooner than June 30 and no later than July 31, to each

enrollee with unused supplemental benefits consistent with the requirements of § 422.2267(e)(42).

[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; 89 FR 30818, Apr. 23, 2024]

§ 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 as defined in § 422.2.

(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; 89 FR 30819, Apr. 23, 2024]

§ 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.

(xiv) Outpatient behavioral health, which can include marriage and family therapists (as defined in section 1861(lll) of the Act), mental health counselors (as defined in section 1861(lll) of the act), opioid treatment programs (as defined in section 1861(jjj) of the act), community mental health centers (as defined in section 1861(ff)(3)(b) of the act), or those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services including psychotherapy or prescription of medication for substance use disorders; physician assistants, nurse practitioners and clinical nurse specialists (as defined in section 1861(aa)(5) of the Act); addiction medicine physicians; or outpatient mental health and substance use treatment facilities.

(A) To be considered as regularly furnishing behavioral health services for the purposes of this regulation, a physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) must have furnished specific psychotherapy or medication prescription services (including, buprenorphine and methadone, for substance use disorders) to at least 20 patients within a 12-month period. CMS will identify, by detailed descriptions or Healthcare Common Procedure Coding System (HCPCS) code(s), the specific services in the HSD Reference File described in paragraph (a)(4)(i) of this section.

(B) To determine that a PA, NP, or CNS meets the standard in paragraph (b)(2)(xiv)(A) of this section, an MA organization must do all of the following:

(1) On an annual basis, independently verify that the provider has furnished such services within a recent 12-month period, using reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data.

(2) If there is insufficient evidence of past practice by the provider, have a reasonable and supportable basis for

concluding that the provider will meet the standard in paragraph (b)(2)(xiv)(A) of this section in the next 12 months.

(3) Submit evidence and documentation to CMS, upon request and in the form and manner specified by CMS, of the MA organization's determination that the provider meets the standard in paragraph (b)(2)(xiv)(A) of this section.

(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
Outpatient Behavioral Health	20	10	40	25	55	40	60	50	110	100
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

TABLE 1 TO PARAGRAPH (d)(2)—Continued

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
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) [Reserved]

(xv) Outpatient Behavioral Health, described in paragraph (b)(2)(xiv) of this section.

(xvi)–(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 either

paragraph (f)(1)(i) or (ii) of this section is met:

(i)(A) 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; and

(B) 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.

(ii)(A) A facility-based Institutional-Special Needs Plan (I-SNP) is unable to contract with certain specialty types required under §422.116(b) because of the way enrollees in facility-based I-SNPs receive care; or

(B) A facility-based I-SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits (in compliance with §422.135) when using telehealth providers of the specialties listed in paragraph (d)(5) of this section in place of in-person providers to fulfill network adequacy standards in paragraphs (b) through (e) of this section.

(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.

(iv) As applicable, the facility-based I-SNP submits:

(A) Evidence of the inability to contract with certain specialty types required under this section due to the way enrollees in facility-based I-SNPs receive care; or

(B) Substantial and credible evidence that sufficient and adequate access to basic benefits is provided to enrollees using additional telehealth benefits (in compliance with §422.135) furnished by providers of the specialties listed in paragraph (d)(5) of this section and the

§ 422.118

42 CFR Ch. IV (10–1–24 Edition)

facility-based I-SNP covers out-of-network services furnished by a provider in person when requested by the enrollee as provided in § 422.135(c)(1) and (2), with in-network cost sharing for the enrollee.

(3) Any MA organization that receives the exception provided for facility-based I-SNPs must agree to offer only facility-based I-SNPs under the MA contract that receives the exception.

[85 FR 33904, June 2, 2020, as amended at 87 FR 27895, May 9, 2022; 88 FR 22330, Apr. 12, 2023; 89 FR 30819, Apr. 23, 2024; 89 FR 63827, Aug. 6, 2024]

§ 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;

(iii) All data classes and data elements included in a content standard in 45 CFR 170.213 that are maintained by the MA organization no later than 1 business day after the MA organization receives the data; and

(iv) Beginning January 1, 2027, the information in paragraph (b)(1)(iv)(A) of this section about prior authorizations for items and services (excluding drugs, as defined in paragraph (b)(1)(v) of this section), according to the timelines in paragraph (b)(1)(iv)(B) of this section.

(A) The prior authorization request and decision, including all of the following, as applicable:

(1) The prior authorization status.

(2) The date the prior authorization was approved or denied.

(3) The date or circumstance under which the prior authorization ends.

(4) The items and services approved.

(5) If denied, a specific reason why the request was denied.

(6) Related structured administrative and clinical documentation submitted by a provider.

(B) The information in paragraph (b)(1)(iv)(A) of this section must—

(1) Be accessible no later than 1 business day after the MA organization receives a prior authorization request;

(2) Be updated no later than 1 business day after any status change; and

(3) Continue to be accessible for the duration that the authorization is active and at least 1 year after the prior authorization's last status change.

(v) Drugs are defined for the purposes of paragraph (b)(1)(iv) of this section as any and all drugs covered by the MA organization, including any products that constitute a Part D drug, as defined by §423.100 of this chapter, and are covered under the Medicare Part D benefit.

(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 and maintain API technology conformant with 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (e)(1);

(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) Using the updated version of the standard, implementation guide, or specification does not disrupt an end user's ability to access the data specified in paragraph (b) of this section or §§422.120, 422.121, and 422.122 through the required APIs.

(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 apps and developers through which parties seek to access electronic health information, as defined in 45 CFR 171.102, including but not limited to, criteria that rely on automated monitoring and risk mitigation tools.

(f) *Reporting on Patient Access API usage.* Beginning in 2026, by March 31 following any calendar year that it offers an MA plan, an MA organization must report to CMS the following metrics, in the form of aggregated, de-identified data, for the previous calendar year at the contract level in the form and manner specified by the Secretary:

(1) The total number of unique enrollees whose data are transferred via the Patient Access API to a health app designated by the enrollee.

(2) The total number of unique enrollees whose data are transferred more

than once via the Patient Access API to a health app designated by the enrollee.

(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.* An MA organization must comply with the requirements of this section beginning in paragraphs (a) through (e) and (g) of this section beginning January 1, 2021, unless otherwise specified, and with the requirements in paragraph (f) of this section beginning in 2026, with regard to data:

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

(2) That are maintained by the MA organization.

[85 FR 25632, May 1, 2020, as amended at 89 FR 8974, Feb. 8, 2024]

§ 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 organization 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]

§ 422.121 Access to and exchange of health data for providers and payers.

(a) *Application programming interface to support data exchange from payers to providers—Provider Access API.* Beginning January 1, 2027, an MA organization must do the following:

(1) *API requirements.* Implement and maintain an application programming interface (API) conformant with all of the following:

(i) Section 422.119(c)(2) through (4), (d), and (e).

(ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (d)(1).

(2) *Provider access.* Make the data specified at § 422.119(b) with a date of service on or after January 1, 2016, excluding provider remittances and enrollee cost-sharing information, that are maintained by the MA organization

available to in-network providers via the API required in paragraph (a)(1) of this section no later than 1 business day after receiving a request from such a provider, if all the following conditions are met:

(i) The MA organization authenticates the identity of the provider that requests access and attributes the enrollee to the provider under the attribution process described in paragraph (a)(3) of this section.

(ii) The enrollee does not opt out as described in paragraph (a)(4) of this section.

(iii) Disclosure of the data is not prohibited by other applicable law.

(3) *Attribution.* Establish and maintain a process to associate enrollees with their in-network providers to enable data exchange via the Provider Access API.

(4) *Opt out and patient educational resources.* (i) Establish and maintain a process to allow an enrollee or the enrollee's personal representative to opt out of the data exchange described in paragraph (a)(2) of this section and to change their permission at any time. That process must be available before the first date on which the MA organization makes enrollee information available via the Provider Access API and at any time while the enrollee is enrolled with the MA organization.

(ii) Provide information to enrollees in plain language about the benefits of API data exchange with their providers, their opt out rights, and instructions both for opting out of data exchange and for subsequently opting in, as follows:

(A) Before the first date on which the MA organization makes enrollee information available through the Provider Access API.

(B) No later than 1 week after the coverage start date or no later than 1 week after receiving acceptance of enrollment from CMS, whichever is later.

(C) At least annually.

(D) In an easily accessible location on its public website.

(5) *Provider resources.* Provide on its website and through other appropriate provider communications, information in plain language explaining the process for requesting enrollee data using the Provider Access API required in

paragraph (a)(1) of this section. The resources must include information about how to use the MA organization's attribution process to associate enrollees with their providers.

(b) *Application programming interface to support data exchange between payers—Payer-to-Payer API.* Beginning January 1, 2027, an MA organization must do the following:

(1) *API requirements.* Implement and maintain an API conformant with all of the following:

(i) Section 422.119(c)(2) through (4), (d), and (e).

(ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (d)(1).

(2) *Opt in.* Establish and maintain a process to allow enrollees or their personal representatives to opt into the MA organization's payer to payer data exchange with the enrollee's previous payer(s), described in paragraphs (b)(4) and (5) of this section, and with concurrent payer(s), described in paragraph (b)(6) of this section, and to change their permission at any time.

(i) The opt in process must be offered as follows:

(A) To current enrollees, no later than the compliance date.

(B) To new enrollees, no later than 1 week after the coverage start date or no later than 1 week after receiving acceptance of enrollment from CMS, whichever is later.

(ii) If an enrollee does not respond or additional information is necessary, the MA organization must make reasonable efforts to engage with the enrollee to collect this information.

(3) *Identify previous and concurrent payers.* Establish and maintain a process to identify a new enrollee's previous and concurrent payer(s) to facilitate the Payer-to-Payer API data exchange. The information request process must start as follows:

(i) For current enrollees, no later than the compliance date.

(ii) For new enrollees, no later than 1 week after the coverage start date or no later than 1 week after receiving acceptance of enrollment from CMS, whichever is later.

(iii) If an enrollee does not respond or additional information is necessary, the MA organization must make rea-

sonable efforts to engage with the enrollee to collect this information.

(4) *Exchange request requirements.* Exchange enrollee data with other payers, consistent with the following requirements:

(i) The MA organization must request the data listed in paragraph (b)(4)(ii) of this section through the enrollee's previous payers' API, if all the following conditions are met:

(A) The enrollee has opted in, as described in paragraph (b)(2) of this section.

(B) The exchange is not prohibited by other applicable law.

(ii) The data to be requested are all of the following with a date of service within 5 years before the request:

(A) Data specified in § 422.119(b) excluding the following:

(1) Provider remittances and enrollee cost-sharing information.

(2) Denied prior authorizations.

(B) Unstructured administrative and clinical documentation submitted by a provider related to prior authorizations.

(iii) The MA organization must include an attestation with this request affirming that the enrollee is enrolled with the MA organization and has opted into the data exchange.

(iv) The MA organization must complete this request as follows:

(A) No later than 1 week after the payer has sufficient identifying information about previous payers and the enrollee has opted in.

(B) At an enrollee's request, within 1 week of the request.

(v) The MA organization must receive, through the API required in paragraph (b)(1) of this section, and incorporate into its records about the enrollee, any data made available by other payers in response to the request.

(5) *Exchange response requirements.* Make available the data specified in paragraph (b)(4)(ii) of this section that are maintained by the MA organization to other payers via the API required in paragraph (b)(1) of this section within 1 business day of receiving a request, if all the following conditions are met:

(i) The payer that requests access has its identity authenticated and includes an attestation with the request that

the patient is enrolled with the payer and has opted into the data exchange.

(ii) Disclosure of the data is not prohibited by other applicable law.

(6) *Concurrent coverage data exchange requirements.* When an enrollee has provided sufficient identifying information about concurrent payers and has opted in as described in paragraph (b)(2) of this section, an MA organization must do the following, through the API required in paragraph (b)(1) of this section:

(i) Request the enrollee's data from all known concurrent payers as described in paragraph (b)(4) of this section, and at least quarterly thereafter while the enrollee is enrolled with both payers.

(ii) Respond as described in paragraph (b)(5) of this section within 1 business day of a request from any concurrent payers. If agreed upon with the requesting payer, the MA organization may exclude any data that were previously sent to or originally received from the concurrent payer.

(7) *Patient educational resources.* Provide information to enrollees in plain language, explaining at a minimum: the benefits of Payer-to-Payer API data exchange, their ability to opt in or withdraw that permission, and instructions for doing so. The MA organization must provide the following resources:

(i) When requesting an enrollee's permission for Payer-to-Payer API data exchange, as described in paragraph (b)(2) of this section.

(ii) At least annually, in appropriate mechanisms through which it ordinarily communicates with current enrollees.

(iii) In an easily accessible location on its public website.

[89 FR 8974, Feb. 8, 2024]

§ 422.122 Prior authorization requirements.

(a) *Communicating a reason for denial.* Beginning January 1, 2026, if the MA organization denies a prior authorization request (excluding request for coverage of drugs as defined in § 422.119(b)(1)(v)), in accordance with the timeframes established in §§ 422.568(b)(1) and 422.572(a)(1), the response to the provider must include a

specific reason for the denial, regardless of the method used to communicate that information.

(b) *Prior Authorization Application Programming Interface (API).* Beginning January 1, 2027, an MA organization must implement and maintain an API conformant with § 422.119(c)(2) through (4), (d), and (e), and the standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (c)(1) that—

(1) Is populated with the MA organization's list of covered items and services (excluding drugs, as defined in § 422.119(b)(1)(v)) that require prior authorization;

(2) Can identify all documentation required by the MA organization for approval of any items or services that require prior authorization;

(3) Supports a Health Insurance Portability and Accountability Act (HIPAA)-compliant prior authorization request and response, as described in 45 CFR part 162; and

(4) Communicates the following information about prior authorization requests:

(i) Whether the MA organization—

(A) Approves the prior authorization request (and the date or circumstance under which the authorization ends);

(B) Denies the prior authorization request; or

(C) Requests more information.

(ii) If the MA organization denies the prior authorization request, it must include a specific reason for the denial.

(5) In addition to the requirements of this section, an MA organization using prior authorization policies or making prior authorization decisions must meet all other applicable requirements under this part, including § 422.138 and the requirements in subpart M of this part.

(c) *Publicly reporting prior authorization metrics.* Beginning in 2026, following each calendar year that it offers an MA plan, an MA organization must report prior authorization data, excluding data on drugs as defined in § 422.119(b)(1)(v), at the MA contract level by March 31. The MA organization must make the following data from the previous calendar year publicly accessible by posting them on its website:

(1) A list of all items and services that require prior authorization.

(2) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(3) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(4) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(5) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

(6) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(7) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(8) The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.

(9) The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

[89 FR 8976, Feb. 8, 2024]

§ 422.125 Resolution of complaints in a Complaints Tracking Module.

(a) *Definitions.* For the purposes of this section, the terms have the following meanings:

Assignment date is the date CMS assigns a complaint to a particular MA organization in the Complaints Tracking Module.

Complaints Tracking Module means an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

Immediate need complaint means a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when

the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

Urgent complaint means a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution—*

(1) *Immediate need complaints.* The MA organization must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The MA organization must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The MA organization must resolve all other complaints within 30 calendar days of the assignment date.

(4) *Extensions.* Except for immediate need complaints, urgent complaints, and any complaint that requires expedited treatment under §§ 422.564(f) or 422.630(d), if a complaint is also a grievance within the scope of §§ 422.564 or 422.630 and the requirements for an extension of the time to provide a response in §§ 422.564(e)(2) or 422.630(e)(2) are met, the MA organization may extend the timeline to provide a response.

(5) *Coordination with timeframes for grievances, PACE service determination requests, and PACE appeals.* When a complaint under this section is also a grievance within the scope of §§ 422.564, 422.630, or 460.120, a PACE service determination request within the scope of § 460.121, or a PACE appeal within the definition of § 460.122, the MA organization must comply with the shortest applicable timeframe for resolution of the complaint.

(c) *Timeline for contacting individual filing a complaint.* Regardless of the type of complaint received, the MA organization must attempt to contact the individual who filed a complaint within 7 calendar days of the assignment date.

[89 FR 30820, Apr. 23, 2024]

§ 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

§ 422.132

42 CFR Ch. IV (10–1–24 Edition)

(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 phar-

macist 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 of conditions are adequately considered in the development of the MA plan's utilization management policies.

(5) Beginning January 1, 2025, include at least one member with expertise in health equity. Expertise in health equity includes educational degrees or credentials with an emphasis on health equity; experience conducting studies identifying disparities amongst different population groups; experience leading organization-wide policies, programs, or services to achieve health equity; or experience leading advocacy efforts to achieve health equity.

(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.

(6) Beginning in 2025, annually conduct a health equity analysis of the use of prior authorization.

(i) The final report of the analysis must be approved by the member of the committee with expertise in health equity before it is publicly posted.

(ii) The analysis must examine the impact of prior authorization on enrollees with one or more of the following social risk factors:

(A) Receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid.

(B) Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(iii) The analysis must use the following metrics, calculated for enrollees with the specified social risk factors

and enrollees without the specified social risk factors, to conduct the analysis at the plan level using data from the prior contract year regarding coverage of items and services excluding data on drugs as defined in § 422.119(b)(1)(v):

(A) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(B) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(C) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(D) The percentage of prior authorization requests for which the time-frame for review was extended, and the request was approved, aggregated for all items and services.

(E) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(F) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(G) The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.

(H) The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

(7) By July 1, 2025, and annually thereafter, publicly post the results of the health equity analysis of the utilization management policies and procedures on the plan's website meeting the following requirements:

(i) In a prominent manner and clearly identified in the footer of the website.

(ii) Easily accessible to the general public, without barriers, including but not limited to ensuring the information is accessible:

(A) Free of charge.

(B) Without having to establish a user account or password.

(C) Without having to submit personal identifying information.

(iii) In a machine-readable format with the data contained within that file being digitally searchable and downloadable.

(iv) Include a txt file in the root directory of the website domain that includes a direct link to the machine-readable file to establish and maintain automated access.

[88 FR 22331, Apr. 12, 2023, as amended at 89 FR 30820, Apr. 23, 2024]

§ 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