

- (ii) Coronary artery disease.
- (iii) Peripheral vascular disease.
- (iv) Valvular heart disease.
- (5) Chronic heart failure.
- (6) Dementia.
- (7) Diabetes mellitus.
- (8) Overweight, obesity, and metabolic syndrome.
- (9) Chronic gastrointestinal disease:
  - (i) Chronic liver disease.
  - (ii) Non-alcoholic fatty liver disease (NAFLD).
  - (iii) Hepatitis B.
  - (iv) Hepatitis C.
  - (v) Pancreatitis.
  - (vi) Irritable bowel syndrome.
  - (vii) Inflammatory bowel disease.
  - (10) Chronic kidney disease (CKD):
    - (i) CKD requiring dialysis/End-stage renal disease (ESRD).
    - (ii) CKD not requiring dialysis.
    - (11) Severe hematologic disorders:
      - (i) Aplastic anemia.
      - (ii) Hemophilia.
      - (iii) Immune thrombocytopenic purpura.
      - (iv) Myelodysplastic syndrome.
      - (v) Sickle-cell disease (excluding sickle-cell trait).
      - (vi) Chronic venous thromboembolic disorder.
    - (12) HIV/AIDS.
    - (13) Chronic lung disorders:
      - (i) Asthma, Chronic bronchitis.
      - (ii) Cystic Fibrosis.
      - (iii) Emphysema.
      - (iv) Pulmonary fibrosis.
      - (v) Pulmonary hypertension.
      - (vi) Chronic Obstructive Pulmonary Disease (COPD).
    - (14) Chronic and disabling mental health conditions:
      - (i) Bipolar disorders.
      - (ii) Major depressive disorders.
      - (iii) Paranoid disorder.
      - (iv) Schizophrenia.
      - (v) Schizoaffective disorder.
      - (vi) Post-traumatic stress disorder (PTSD).
      - (vii) Eating Disorders.
      - (viii) Anxiety disorders.
    - (15) Neurologic disorders:
      - (i) Amyotrophic lateral sclerosis (ALS).
      - (ii) Epilepsy.
      - (iii) Extensive paralysis (that is, hemiplegia, quadriplegia, paraplegia, monoplegia).
      - (iv) Huntington's disease.

- (v) Multiple sclerosis.
- (vi) Parkinson's disease.
- (vii) Polyneuropathy.
- (viii) Fibromyalgia.
- (ix) Chronic fatigue syndrome.
- (x) Spinal cord injuries.
- (xi) Spinal stenosis.
- (xii) Stroke-related neurologic deficit.
- (16) Stroke.
- (17) Post-organ transplantation care.
- (18) Immunodeficiency and Immunosuppressive disorders.
- (19) Conditions associated with cognitive impairment:
  - (i) Alzheimer's disease.
  - (ii) Intellectual disabilities and developmental disabilities.
  - (iii) Traumatic brain injuries.
  - (iv) Disabling mental illness associated with cognitive impairment.
  - (v) Mild cognitive impairment.
- (20) Conditions with functional challenges and require similar services including the following:
  - (i) Spinal cord injuries.
  - (ii) Paralysis.
  - (iii) Limb loss.
  - (iv) Stroke.
  - (v) Arthritis.
- (21) Chronic conditions that impair vision, hearing (deafness), taste, touch, and smell.
- (22) Conditions that require continued therapy services in order for individuals to maintain or retain functioning.

*Special needs individual* means an MA eligible individual who is institutionalized or institutionalized-equivalent, as those terms are defined in this section, is entitled to medical assistance under a State plan under title XIX, or has a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan.

*Specialized MA Plans for Special Needs Individuals* means an MA coordinated care plan that exclusively enrolls special needs individuals as set forth in § 422.4(a)(1)(iv) and that provides Part D benefits under part 423 of this chapter to all enrollees; and which has been designated by CMS as meeting the requirements of an MA SNP as determined on a case-by-case basis using

criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population.

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

[63 FR 35068, June 26, 1998, as amended at 65 FR 40314, June 29, 2000; 68 FR 50855, Aug. 22, 2003; 70 FR 4714, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 70 FR 76197, Dec. 23, 2005; 72 FR 68722, Dec. 5, 2007; 74 FR 1540, Jan. 12, 2009; 75 FR 19803, Apr. 15, 2010; 76 FR 21561, Apr. 15, 2011; 79 FR 29955, May 23, 2014; 83 FR 16722, Apr. 16, 2018; 84 FR 15827, Apr. 16, 2019; 84 FR 23879, May 23, 2019; 86 FR 6094, Jan. 19, 2021; 87 FR 27893, May 9, 2022; 89 FR 30812, Apr. 23, 2024]

### § 422.3 MA organizations' use of reinsurance.

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

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

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

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

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

(b) In evaluating compliance with section 1855(b) of the Act and with paragraph (a) of this section, CMS will

consider a parent organization and any of its subsidiaries to be part of the MA organization.

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

[85 FR 33901, June 2, 2020]

### § 422.4 Types of MA plans.

(a) *General rule.* An MA plan may be a coordinated care plan, a combination of an MA MSA plan and a contribution into an MA MSA established in accordance with § 422.262, or an MA private fee-for-service plan.

(1) *A coordinated care plan.* A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by CMS.

(i) The network is approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(ii) Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care.

(iii) Coordinated care plans include plans offered by any of the following:

(A) Health maintenance organizations (HMOs);

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

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

(D) Other network plans (except PFFS plans).

(iv) A specialized MA plan for special needs individuals (SNP) includes any type of coordinated care plan that

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

(A) A C-SNP may focus on one severe or disabling chronic condition, as defined in § 422.2, or on a grouping of severe or disabling chronic conditions.

(B) Upon CMS approval, an MA organization may offer a C-SNP that focuses on multiple commonly co-morbid and clinically linked conditions from the following list of groupings:

(1) Diabetes mellitus and chronic heart failure.

(2) Chronic heart failure and cardiovascular disorders.

(3) Diabetes mellitus and cardiovascular disorders.

(4) Diabetes mellitus, chronic heart failure, and cardiovascular disorders.

(5) Stroke and cardiovascular disorders.

(6) Anxiety associated with COPD.

(7) Chronic kidney disease (CKD) and post-(renal) organ transplantation.

(8) Substance use disorders (SUD) and chronic mental health disorders.

(v) A PPO plan is a plan that—

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

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

(C) Only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO; and

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

to furnishing those services, or the enrollee voluntarily notifies the PPO plan prior to receiving plan-covered services from an out-of-network provider.

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

(2) *A combination of an MA MSA plan and a contribution into the MA MSA established in accordance with § 422.262.* (i) *MA MSA plan* means a plan that—

(A) Pays at least for the services described in § 422.101, after the enrollee has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in § 422.103(d);

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

(C) Meets all other applicable requirements of this part.

(ii) *MA MSA* means a trust or custodial account—

(A) That is established in conjunction with an MSA plan for the purpose of paying the qualified expenses of the account holder; and

(B) Into which no deposits are made other than contributions by CMS under the MA program, or a trustee-to-trustee transfer or rollover from another MA MSA of the same account holder, in accordance with the requirements of sections 138 and 220 of the Internal Revenue Code.

(3) *MA private fee-for-service plan.* An MA private fee-for-service plan is an MA plan that—

(i) Pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

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

(A) May vary the rates for a provider based on the specialty of the provider,