(iii) Relevant current clinical guidelines.

(2) Approve only utilization management policies and procedures that:

(i) Use or impose coverage criteria that comply with the requirements and standards at §422.101(b);

(ii) For prior authorization policies, comply with requirements and standards at §422.138;

(iii) Comply with the standards in §422.202(b)(1); and

(iv) Apply and rely on medical necessity criteria that comply with §422.101(c)(1).

(3) Revise the utilization management policies and procedures as necessary to comply with the standards in this regulation, including removing requirements for UM for services and items that no longer warrant UM.

(4) Clearly articulate and document processes to determine that the requirements under paragraphs (c)(1) through (4) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(5) Document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request.

[88 FR 22331, Apr. 12, 2023]

§422.138 Prior authorization.

(a) *Requirement.* When a coordinated care plan, as specified in §422.4(a)(iii) (including MSA network plans), uses prior authorization processes in connection with basic benefits or supplemental benefits, the MA organization must comply with the requirements in this section. (MA PFFS are not permitted to use prior authorization policies or ''prior notification'' policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the PFFS plan in advance that services will be furnished). Prior authorization processes include all policies and procedures used in prior authorization unless otherwise noted.

(b) *Application.* Prior authorization processes for coordinated care plans may only be used for one or more the following purposes:

(1) To confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service; or

(2) For basic benefits, to ensure an item or service is medically necessary based on standards specified in §422.101(c)(1), or

(3) For supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate.

(c) *Effect of prior authorization or pre-service approval.* If the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at §405.986 of this chapter) or if there is reliable evidence of fraud or similar fault per the reopening provisions at §422.616. The definitions of the terms ''reliable evidence'' and ''similar fault'' in §405.902 of this chapter apply to this provision.

[88 FR 22331, Apr. 12, 2023]

Subpart D—Quality Improvement

SOURCE: 63 FR 35082, June 26, 1998, unless otherwise noted.

§422.152 Quality improvement program.

(a) *General rule.* Each MA organization that offers one or more MA plan must have, for each plan, an ongoing quality improvement program that meets applicable requirements of this section for the service it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must do all of the following:

(1) Create a quality improvement program plan that sufficiently outlines the elements of the plan's quality improvement program.

(2) Have a chronic care improvement program that meets the requirements

of paragraph (c) of this section concerning elements of a chronic care program and addresses populations identified by CMS based on a review of current quality performance.

(3) [Reserved]

(4) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

(5) Incorporate one or more activities that reduce disparities in health and health care. These activities must be broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparities in health and health care.

(b) *Requirements for MA coordinated care plans (except for regional MA plans) and including local PPO plans that are offered by organizations that are licensed or organized under State law as HMOs.* An MA coordinated care plan's (except for regional PPO plans and local PPO plans as defined in paragraph (e) of this section) quality improvement program must—

(1) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(2) Have in effect mechanisms to detect both underutilization and overutilization of services.

(3) Measure and report performance. The organization offering the plan must do the following:

(i) Measure performance under the plan, using the measurement tools required by CMS, and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those under paragraph (b)(3)(i) of this section.

(iii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64.

(4) Special rule for MA local PPO-type plans that are offered by an organization that is licensed or organized under State law as a health maintenance organization must meet the requirements specified in paragraphs (b)(1) through (b)(3) of this section.

(5) All coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

(6) For 2021 Star Ratings only, MA organizations are not required to submit HEDIS and CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings.

(c) *Chronic care improvement program requirements.* (1) Develop criteria for a chronic care improvement program. These criteria must include the following:

(i) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program.

(ii) Mechanisms for monitoring MA enrollees that are participating in the chronic improvement program and evaluating participant outcomes such as changes in health status.

(iii) Performance assessments that use quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or research.

(iv) Systematic and ongoing follow-up on the effect of the program.

(2) The organization must report the status and results of each program to CMS as requested.

(d) [Reserved]

(e) *Requirements for MA regional plans and MA local plans that are PPO plans as defined in this section*—(1) *Definition of local preferred provider organization plan.* For purposes of this section, the

term local preferred provider organization (PPO) plan means an MA plan that—

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

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

(iii) Is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(2) MA organizations offering an MA regional plan or local PPO plan as defined in this section must:

(i) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Collect, analyze, and report quality performance data identified by CMS that are of the same type as those described under paragraph (e)(2)(i) of this section.

(iii) Evaluate the continuity and coordination of care furnished to enrollees.

(iv) If the organization uses written protocols for utilization review, the organization must—

(A) Base those protocols on current standards of medical practice; and

(B) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans*—(1) *Health information*. For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to CMS.

(2) *Program review*. For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

(3) *Remedial action*. For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

(g) *Special requirements for specialized MA plans for special needs individuals*. All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. SNPs must submit their model of care (MOC), as defined under §422.101(f), to CMS for NCQA evaluation and approval, in accordance with CMS guidance. In addition to the requirements under paragraphs (a) and (f) of this section, a SNP must conduct a quality improvement program that does the following:

(1) Provides for the collection, analysis, and reporting of data that measures health outcomes and indices of quality pertaining to its targeted special needs population (that is, dual-eligible, institutionalized, or chronic condition) at the plan level.

(2) Measures the effectiveness of its model of care through the collection, aggregation, analysis, and reporting of data that demonstrate the following:

(i) Access to care as evidenced by measures from the care coordination domain (for example, service and benefit utilization rates, or timeliness of referrals or treatment).

(ii) Improvement in beneficiary health status as evidenced by measures from functional, psychosocial, or clinical domains (for example, quality of life indicators, depression scales, or chronic disease outcomes).

(iii) Staff implementation of the SNP model of care as evidenced by measures of care structure and process from the continuity of care domain (for example, National Committee for Quality Assurance accreditation measures or medication reconciliation associated with care setting transitions indicators).

(iv) Comprehensive health risk assessment as evidenced by measures from the care coordination domain (for example, accuracy of acuity stratification, safety indicators, or timeliness of

initial assessments or annual reassessments).

(v) Implementation of an individualized plan of care as evidenced by measures from functional, psychosocial, or clinical domains (for example, rate of participation by IDT members and beneficiaries in care planning).

(vi) A provider network having targeted clinical expertise as evidenced by measures from medication management, disease management, or behavioral health domains.

(vii) Delivery of services across the continuum of care.

(viii) Delivery of extra services and benefits that meet the specialized needs of the most vulnerable beneficiaries as evidenced by measures from the psychosocial, functional, and end-of-life domains.

(ix) Use of evidence-based practices and nationally recognized clinical protocols.

(x) Use of integrated systems of communication as evidenced by measures from the care coordination domain (for example, call center utilization rates, rates of beneficiary involvement in care plan development, etc.).

(3) Makes available to CMS information on quality and outcomes measures that will—

(i) Enable beneficiaries to compare health coverage options; and

(ii) Enable CMS to monitor the plan's model of care performance.

(h) *Requirements for MA private-fee-for-service plans and Medicare medical savings account plans.* MA PFFS and MSA plans are subject to the requirement that may not exceed the requirement specified in § 422.152(e).

[70 FR 4723, Jan. 28, 2005, as amended at 70 FR 52026, Sept. 1, 2005; 73 FR 54249, Sept. 18, 2008; 75 FR 19805, Apr. 15, 2010; 76 FR 21564, Apr. 15, 2011; 80 FR 7959, Feb. 12, 2015; 83 FR 16725, Apr. 16, 2018; 85 FR 19290, Apr. 6, 2020; 88 FR 22332, Apr. 12, 2023]

§ 422.153 Use of quality improvement organization review information.

CMS will acquire from quality improvement organizations (QIOs) as defined in part 475 of this chapter data collected under section 1886(b)(3)(B)(viii) of the Act and subject to the requirements in § 480.140(g). CMS will acquire this information, as needed, and may use it for the following functions:

(a) Enable beneficiaries to compare health coverage options and select among them.

(b) Evaluate plan performance.

(c) Ensure compliance with plan requirements under this part.

(d) Develop payment models.

(e) Other purposes related to MA plans as specified by CMS.

[76 FR 26546, May 6, 2011]

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An MA organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The MA organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization used the standards approved by CMS for the purposes of assessing the MA organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) *Quality improvement.* The deeming process should focus on evaluating and assessing the overall quality improvement (QI) program. However, the chronic care improvement programs (CCIPs) will be excluded from the deeming process.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

(7) The requirements listed in § 423.165 (b)(1) through (3) of this chapter for MA organizations that offer prescription drug benefit programs.

(c) *Effective date of deemed status.* The date on which the organization is deemed to meet the applicable requirements is the later of the following:

(1) The date on which the accreditation organization is approved by CMS.