

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

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