

(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 pharmacist 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, pharmaco-economic 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]

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 con-

cerning 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.

(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