E. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, and 422.138)

1. Introduction

A majority of MA plans are coordinated care plans, which is defined at § 422.4(a) as a plan that includes a network of providers that are under contract or arrangement with an MA organization to deliver the benefit package approved by CMS. CMS regulations at § 422.202(b) require that each MA organization consult with network providers on the organization's medical policy, quality improvement programs, medical management procedures, and ensure that certain standards are met. For example, coordinated care plans must ensure that practice guidelines and utilization management guidelines are based on reasonable medical evidence or a consensus of health care professionals in the particular field; consider the needs of the enrolled population; are developed in consultation with contracting physicians; and are reviewed and updated periodically. Further, these guidelines must be communicated to providers and, as appropriate, to enrollees.

Coordinated care plans are designed to manage cost, service utilization, and quality by ensuring that only medically necessary care is provided. This is done in part through the use of utilization management tools, including prior authorization, expressly referenced at section 1852(c)(1)(G) and (c)(2)(B) of the Act. These tools are designed to help MA plans determine the medical necessity of services and minimize the furnishing of unnecessary services, thereby helping to contain costs and protect beneficiaries from receiving unnecessary care. Additionally, section 1852(g)(1)(A) of the Act states that MA plans shall have a procedure for making determinations regarding whether an enrollee is entitled to receive a health care service and that such determinations must be made on a timely basis; that provision applies to both prior authorization determinations and to post-service decisions about coverage and payment.

In addition, CMS regulations at § 422.101(a) and (b) require that MA plans provide coverage of all basic benefits (that is, services covered under Medicare Parts A and B, except hospice care and the cost of kidney acquisitions for transplant) and that MA plans must comply with Traditional Medicare national coverage determinations (NCDs) and local coverage determinations (LCDs) applicable in the MA plan's service area.[94] In recent years, CMS has received feedback from various stakeholders, including patient groups, consumer advocates, providers and provider trade associations that utilization management in MA, especially prior authorization, can sometimes create a barrier to patients accessing medically necessary care. Stakeholder feedback has included concerns about the quality of MA plans' prior authorization decisions (for example, coverage denials being made by plan clinicians who do not have expertise in the field of medicine applicable to the requested service) and process challenges (for example, repetitive prior approvals for needed services for enrollees that have a previously-approved plan of care).

In addition, in April 2022, the Office of the Inspector General (OIG) released a report[95] titled, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," which summarized the results of a study by the OIG of MA plan denials of requests for prior authorization of services. The OIG found that some prior authorization requests were denied by MA plans, even though the requested services met Traditional Medicare coverage guidelines. In other cases, the OIG found that prior authorization requests were inappropriately denied by MA organizations due to errors that were likely preventable through process or system changes by MA organizations. Citing a concern that such inappropriate denials may prevent or delay beneficiaries from receiving medically necessary care, the OIG recommended that CMS: (1) issue new guidance on the appropriate use of MA organization clinical criteria in medical necessity reviews; (2) update its

[94]The terms "Traditional Medicare" and "Original Medicare" are used interchangeably throughout this section and both mean the Medicare Fee-For-Service program.
[95]https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

audit protocols to address the issues related to MA organizations' use of clinical criteria and/or examining particular service types; and (3) direct MA organizations to take steps to identify and address vulnerabilities that can lead to manual review errors and system errors.[96]

CMS understands that utilization management tools are an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care. In light of the feedback we have received from stakeholders and the findings in the OIG report, however, we have concluded that certain guardrails are needed to ensure that utilization management tools are used, and associated coverage decisions are made, in ways that ensure timely and appropriate access to medically necessary care for beneficiaries enrolled in MA plans. We proposed to clarify requirements for the coverage criteria that MA plans use when making medical necessity determinations. We also proposed additional beneficiary protection requirements in order to improve continuity of care and integration of health care services and to increase plan compliance with regards to utilization management policies. Our proposals interpreted and implemented the requirements in section 1852 of the Act regarding the provision and coverage of services by MA plans and were, therefore, proposed under our authority in section 1856 of the Act to adopt standards to carry out the Part C statute and MA program.

As originally stated in the June 2000 final rule (65 FR 40207), MA organizations must cover all Part A and B benefits, excluding hospice services and the cost of kidney acquisitions for transplant, on the same conditions that items and services are furnished in Traditional Medicare. This means that MA organizations may not limit coverage through the adoption of policies and procedures—whether those policies and procedures are called utilization management and prior authorization or the standards and criteria that the MA organization uses to assess and evaluate medical necessity – when those policies and procedures result in denials of coverage or payment where the Traditional Medicare program would cover and pay for the item

[96]https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf, pg. 3

or service furnished to the beneficiary. In addition, this means that limits or conditions on payment and coverage in the Traditional Medicare program—such as who may deliver a service and in what setting a service may be provided, the criteria adopted in relevant NCDs and LCDs, and other substantive conditions—apply to set the scope of basic benefits as defined in § 422.100(c).

MA organizations have flexibility to furnish and cover services without meeting all substantive conditions of coverage in Traditional Medicare, but that flexibility is limited to and in the form of supplemental benefits. As stated in the June 2000 final rule, MA organizations' flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the MA program. If Traditional Medicare covers a service only when certain conditions are met, these conditions must be met in order for the service to be considered part of the Traditional Medicare benefits (that is, basic benefits) component of an MA plan. MA organizations may cover the same service when the conditions are not met, but these benefits would then be defined as supplemental benefits within the scope of §§ 422.100(c)(2) and 422.102 and must be included in the supplemental benefits portion of the MA plan's bid. For example, when services are furnished by a type of provider other than the type of provider who may furnish the service in Traditional Medicare, those services are supplemental benefits. We proposed policies that provide less flexibility for MA organizations to deny or limit coverage of basic benefits than provided in the 2000 final rule. However, as provided by section 1852(a)(3) of the Act and reflected in §§ 422.100(c)(2) and 422.102, MA plans may cover benefits beyond what is covered (and when it is covered) under Traditional Medicare by offering supplemental benefits. Our proposal was primarily directed at ensuring that minimum coverage requirements are met and that MA plans do not deny or limit coverage of basic benefits; we were not proposing to limit the scope of permissible supplemental benefits, but our proposal applies certain requirements for the use of utilization management for all covered benefits as discussed in section III.E. of this proposed rule.

In this rule, we clarify acceptable cost-effective utilization management approaches for MA organizations to use in the context of the new proposed requirements. These clarifications aim to ensure access to medically necessary care, while maintaining MA organizations' ability to apply utilization management that ensures clinically appropriate care. Additionally, we are codifying substantive rules regarding clinical coverage criteria for basic benefits and how they interact with utilization management policies, including revisions to existing regulations and adopting new regulations to ensure that MA enrollees receive the basic benefits coverage to which they are entitled and to ensure appropriate treatment of a benefit as a basic benefit or supplemental benefit for purposes of the bid under § 422.254. We solicited comment on whether our proposed regulatory provisions sufficiently address the requirements and limits that we described in the preamble.

The final rules adopted here related to utilization management requirements and limitations, coverage criteria and medical necessity determinations, use of prior authorization and continuity of care requirements for MA plans are additional standards to implement the statutory requirements at section 1852(a) of the Act that MA plans provide to their enrollees (by furnishing directly or through contracted providers, arranging for, or paying for) basic benefits (that is, all Part A and Part B benefits with limited exceptions) and such supplemental benefits the MA plan elects to offer. CMS has authority to adopt standards to carry out the applicable MA provisions in Title XVIII of the Act and to add new contract terms that we find necessary, appropriate, and not inconsistent with the statute in sections 1856(b) and 1857(e) of the Act. In addition, section 1854(a)(5) and (6) of the Act provide that CMS is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits. To the extent that these new minimum standards for MA organizations and how they cover benefits would not implement section 1852 of the Act, establish standards to carry out the MA program under section 1856(b) of the Act (which CMS does not concede, as these are important protections to ensure that MA enrollees receive Medicare covered services), or be contract terms

that we are authorized to adopt under section 1857(e)(1) of the Act, we believe that our negotiation authority in section 1854(a)(6)(B) of the Act permits creation of minimum coverage requirements. While the rules finalized here do not limit our negotiation authority (which is addressed in § 422.256), they provide minimum standards for an acceptable benefit design for CMS to apply in reviewing and evaluating bids, in addition to establishing important protections to ensure that enrollees have access to medically necessary items and services that are covered under Part A and Part B.

2. Coverage Criteria for Basic Benefits

a. Application of Coverage Criteria

In interpreting requirements involving coverage criteria, whether used for prior authorization or post-service payment, CMS has a longstanding policy, discussed in sub-regulatory guidance (section 10.16 of Chapter 4 of MMCM), that MA plans must make medical necessity determinations based on internal policies that include coverage criteria that are no more restrictive than Traditional Medicare's national and local coverage policies and approved by a plan's medical director. In light of the previously discussed feedback and the OIG recommendation that we issue new guidance on the appropriate use of MA organization clinical criteria in medical necessity reviews, we proposed to codify standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than Traditional Medicare. Section 1862 of the Act requires original Medicare benefits to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Thus, in order to meet the statutory requirements at section 1852(a)(1) of the Act, which requires MA plans to cover A and B services, MA plan coverage criteria must do the same. We also proposed to amend § 422.101(b) and (c) to clarify the obligations and responsibilities for MA plans in covering basic benefits.

Section 1852(a)(1) of the Act and CMS regulations at § 422.101(a) and (b) require all MA organizations to provide coverage of, by furnishing, arranging for, or making payment for,

all items and services that are covered by Part A and Part B of Medicare and that are available to beneficiaries residing in the plan's service area. Section 422.101 requires MA organizations to comply with all NCDs; LCDs written by Medicare Administrative Contractors (MACs) with jurisdiction for Medicare claims in the MA organization's or plan's service area; and coverage instructions and guidance in Medicare manuals, instructions and other guidance documents unless those materials are superseded by regulations in part 422.

We proposed to amend § 422.101(b)(2) by removing the reference to "original Medicare manuals and instructions" and clarify that MA organizations must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans, when making coverage decisions. Our proposal was designed to prohibit MA organizations from limiting or denying coverage when the item or service would be covered under Traditional Medicare and to continue the existing policies that permit MA organizations to cover items and services more broadly than original Medicare by using supplemental benefits. In proposing this change to § 422.101(b)(2), we reiterated that limits or conditions on payment and coverage in the Traditional Medicare program—such as who may deliver a service and in what setting a service may be provided, the criteria adopted in relevant NCDs and LCDs, and other substantive conditions—apply to define the scope of basic benefits. By removing the reference to "original Medicare manuals and instructions," we were not diminishing the content and value that these manuals and instructions provide in interpreting and defining the scope of Part A and Part B benefits. These manuals contain significant explanations and interpretations of Traditional Medicare laws governing Part A and Part B benefits, most of it longstanding, to provide instructions and procedures for day to day operations for those responsible for administering the Medicare program. Our goal to ensure that MA enrollees receive the same items and services as beneficiaries in the FFS program is accomplished when the same coverage policies and approaches are used. We expect that MA plans will consult the Medicare Benefit Policy Manual, Medicare Program Integrity Manual, and similar CMS

guidance materials. We note that MA organizations must agree to comply with all applicable requirements, conditions, and general instructions under the terms of their contract with CMS under § 422.504(a). The proposed revision to § 422.101(b)(2) clarifies that statutes and regulations that set the scope of coverage in the Traditional Medicare program are applicable to MA organizations in setting the scope of basic benefits that must be covered by MA plans. We also proposed to refer in § 422.101(b)(2) to specific Medicare regulations that include coverage criteria for Part A inpatient admissions, Skilled Nursing Facility (SNF) care, Home Health Services and Inpatient Rehabilitation Facilities (IRF) as examples of general coverage and benefit conditions in Traditional Medicare that apply to basic benefits in the MA program. The list of Medicare regulations referred to is not exhaustive and provides examples of substantive coverage and benefit conditions that apply to MA. In addition, we also proposed to revise the current provision that states that Traditional Medicare coverage rules apply unless superseded by regulations in this part. We proposed to revise that aspect of § 422.101(b)(2) to refer to laws applicable to MA plans in order to avoid implying that a Part 422 regulation could supersede an applicable statute.

For example, the existing rule at § 422.101(c), which states that MA organizations may elect to furnish, as part of their Medicare covered benefits, coverage of post-hospital SNF care in the absence of the prior qualifying hospital stay is a special rule in MA that deviates from coverage criteria articulated in Traditional Medicare. The regulation is based on section 1812(f) of the Act, which authorizes CMS to permit coverage of SNF care without the 3-day qualifying hospital stay in limited circumstances. (68 FR 50847-50848). This rule provides MA organizations the flexibility to cover, as a basic benefit, SNF stays for MA enrollees that would not be otherwise coverable in Traditional Medicare, if the beneficiary had not met the prior qualifying hospital stay of 3 days prior to admission in the SNF. This special rule continues to apply in the MA program; however, we proposed to redesignate this rule to paragraph (c)(2) of § 422.101 as part of our proposal to add a heading to § 422.101(c) and to expand the scope of the

paragraph. We proposed to add the heading "Medical Necessity Determinations and Special Coverage Provisions" to § 422.101(c). As such, we proposed to reassign the special rule for coverage of posthospital SNF in the absence of the prior qualifying hospital stay as § 422.101(c)(2). The proposed new heading for § 422.101(c), "Medical Necessity Determinations and Special Provisions," is intended to signal that paragraph (c) will address medical necessity criteria and special rules that apply to MA basic benefits that do not necessarily conform to coverage rules in Traditional Medicare.

We proposed to codify at § 422.101(c)(1)(A) that MA organizations must make medical necessity determinations based on coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria that are not specified in § 422.101(b) or (c). This means that when an MA organization is making a coverage determination on a Medicare covered item or service with fully established coverage criteria, the MA organization cannot deny coverage of the item or service on the basis of internal, proprietary, or external clinical criteria that are not found in Traditional Medicare coverage policies. Under this proposal, certain utilization management processes, such as clinical treatment guidelines that require another item or service be furnished prior to receiving the requested item or service, would violate the proposed requirements at § 422.101(b) and (c), and thus, their use by an MA organization would be prohibited unless specified within the applicable NCD or LCD or Medicare statute or regulation. We note that we did not propose to revise § 422.136, which authorizes MA plans to use step therapy policies for Part B drugs under certain circumstances; in the next paragraph, we discuss the basis for authorizing MA plan-specific step therapy for Part B drugs in § 422.136 in more detail. Otherwise, clinical criteria that restrict access to a Medicare covered item or service unless another item or service is furnished first, when not specifically required in NCD or LCD, would be considered additional internal coverage criteria that are prohibited. When MA plans are allowed to create internal coverage criteria as specified at proposed § 422.101(b)(6), the current evidence in widely used treatment

guidelines or clinical literature relied upon to make the coverage determination may recommend clinical treatment guidelines that require another item or service first. When use of MA plan internal coverage criteria is permitted under this rule, as long as the supporting, widely used treatment guidelines or clinical literature recommend another item or service first, this approach would be acceptable under our proposed policy. We discuss adding § 422.101(b)(6) later in this section of the rule.

In an HPMS memo released August 7, 2018, CMS announced that under certain conditions beginning in contract year 2019, MA plans may use utilization management tools such as step therapy for Part B drugs. In a May 2019 final rule (84 FR 23832), we codified MA organizations' ability to use step therapy for Part B drugs under certain conditions that protect beneficiaries and acknowledged that utilization management tools, such as step therapy, can provide a means for MA plans to better manage and negotiate the costs of providing Part B drugs.

We clarified that, with respect to clinical concerns and interference with provider care, step therapy or other utilization management policies may not be used as unreasonable means to deny coverage of medically necessary services or to eliminate access to medically necessary Part B covered drugs (84 FR 23856). The requirements in the 2019 rule, in combination with current MA program regulations, ensure access to Part B drugs and limit the potential for step therapy policies to interfere with medically necessary care. Organizations have been and remain subject to the MA regulations and must comply with national and applicable local coverage determinations. Step therapy protocols cannot be stricter than an NCD or LCD with specified step therapy requirements. Thus, this proposal was consistent with the 2019 rule in that MA plans must still comply with NCDs and LCDs when developing step therapy programs for Part B drugs.

Finally, in the May 2019 final rule, we did not authorize step therapy practices for Part A or Part B (non-drug) items or services and our proposal here was to limit the ability of MA

organizations to use such UM policies in connection with non-drug covered items or services that are basic benefits. There are a number of differences with step therapy for Part B drugs and step therapy for non-drug items and services that we cited in the proposed rule to support how our proposals on coverage criteria and utilization management would treat items and services that are not Part B drugs differently. From a clinical standpoint, there tends to be more than one drug that has demonstrated success in treating a certain disease or condition, and also there are generic alternatives, which is somewhat different than other Part A and B services. Often, there are not head-to-head comparisons between drugs in a certain class of medications, because a non-inferiority study[97] was conducted in order to bring the drug to market. This means that it is not always obvious what the clinically superior drug is for certain diseases or conditions, while there may be a significant difference in pricing. Furthermore, there are several studies[98] demonstrating how increased cost sharing for medications can, in and of itself, reduce patient adherence to those medications.

In addition, the manner in which Part B drugs are purchased and furnished is somewhat different from coverage of non-drug health care items and services. Generally, MA organizations pay the provider for both the service of administering a Part B drug and the cost of the drug, but do not directly pay drug manufacturers or suppliers for the cost of the drug. MA organizations may negotiate pricing discounts or rebates with the manufacturer, who is not the entity that directly furnishes the Part B drug to enrollees and who is not ordinarily paid directly by the MA organization for what is furnished to enrollees. As we explained in the May 2019 final rule (84 FR 23858, 23863, and 23869), we believe that § 422.136 can put MA organizations in a stronger position to negotiate lower pharmaceutical prices with drug manufacturers, reducing the cost sharing for the beneficiary. Furthermore, as previously discussed, studies have demonstrated that increased cost sharing for medications can reduce patient adherence to those

[97]https://www.fda.gov/media/78504/download.
[98]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/

medications. Therefore, we did not propose to revise our current regulations regarding Part B step therapy.

Similar to MACs in Traditional Medicare, we expect MA organizations to make medical necessity decisions based on NCDs, LCDs, and other applicable coverage criteria in Medicare statutes and regulations to determine if an item or service is reasonable, necessary and coverable under Medicare Part A or Part B. In some circumstances, NCDs or LCDs expressly include flexibility that allows coverage in circumstances beyond the specific coverage or non-coverage indications that are listed in the NCD or LCD. For example, an NCD or LCD may state that the item or service can be covered when reasonable and necessary for the individual patient. When deciding whether an item or service is reasonable and necessary for an individual patient, we expect the MA plan to make this medical necessity decision in a manner that most favorably provides access to services for the beneficiary and align with CMS's definition of reasonable and necessary as outlined in the Medicare Program Integrity Manual, Chapter 13, section 13.5.4. CMS's expectation, as previously outlined, applies to coverage determinations made before the item or service is provided (pre-certification/prior authorization), during treatment (case management), or after the item or service has been provided (claim for payment). We intended this proposal to clarify, as recommended by the OIG, that limited clinical coverage criteria can be applied to basic benefits and reinforces our longstanding policy that MA organizations may only apply coverage criteria that are no more restrictive than Traditional Medicare coverage criteria found in NCDs, LCDs, and Medicare laws. We reiterated in the proposed rule our intent that the proposed changes to the MA regulations would apply to substantive coverage criteria and benefit conditions found in Traditional Medicare regulations, such as those governing inpatient admissions and transfers to post-acute care settings, which are not governed by NCD or LCD. We explained that under our proposal, an MA organization may only deny a request for Medicare-covered post-acute care services in a particular setting if the MA organization determines that the Traditional Medicare coverage criteria for the services cannot be satisfied in

that particular setting. As we discuss in section III.E.3 of this rule, this does not restrict an MA organization's ability to use certain utilization management processes, like prior authorization or post claim review, to ensure items and services meet Medicare coverage rules; it simply limits the coverage criteria that an MA organization can apply or rely upon to deny an item or service during those reviews. We solicited comment about the specificity of the coverage conditions in Traditional Medicare regulations and whether we should consider, and under what circumstances, allowing MA organizations to have internal coverage criteria in addition to requirements in current Medicare regulations.

We recognize that there are some Part A or Part B benefits that do not have applicable Medicare NCDs, LCDs, or specific traditional Medicare coverage criteria in regulation for MA plans to follow when making medical necessity determinations. Therefore, we proposed at § 422.101(b)(6) that when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. In creating these internal policies, we proposed that MA organizations must follow similar rules that CMS and MACs must follow when creating NCDs or LCDs. Specifically, MA organizations must provide publicly available information that discusses the factors the MA organization considered in making coverage criteria for medical necessity determinations.

Section 1862(l) of the Act requires the Secretary to issue publicly a discussion and explanation of the factors considered in making NCDs, after following a process that affords the public an opportunity to comment prior to implementation. We proposed at § 422.101(b)(6) that MA organizations must follow a somewhat similar process when creating internal plan coverage criteria by providing a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the

adoption of the coverage criteria used to make a medical necessity determination. We did not propose that MA organizations must provide a pre-determination explanation and opportunity for the public to comment on the MA organization's coverage criteria; however, providing a publicly accessible summary of the evidence, a list of the sources of evidence, and an explanation of the rationale for the internal coverage criteria will protect beneficiaries by ensuring that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature. This requirement provides further transparency into MA organizations' medical necessity decision making and is consistent with CMS's expectation that MA organizations develop and use coverage criteria in a way that aligns with Traditional Medicare.

We also proposed at § 422.101(b)(6) a requirement that an MA organization's internal clinical criteria must be based on current evidence in widely used treatment guidelines or clinical literature. 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 (such as referring to the Infectious Diseases Society of America for the Treatment of *Clostridium Difficile*[99]) or to determine appropriate level of care (such as the American Society of Addiction Medicine Criteria for placement[100] continued stay, and transfer or discharge of patients with addiction and co-occurring conditions). Clinical literature that CMS considers to be of high enough quality for the justification of internal coverage criteria include large, randomized controlled trials or cohort studies or all-or-none 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 published in a peer-reviewed journal with clear and consistent results.

[99]Reference:
https://www.idsociety.org/practice-guideline/clostridium-difficile and https://www.idsociety.org/practice-guideline/clostridioides-difficile-2021-focused-update/
[100]https://www.asam.org/asam-criteria

Evidence that is unpublished, is a case series or report, or derived solely from internal analyses within the MA organization, or that does not comply with the standards, as previously described, would not represent proper justification for instituting internal coverage guidelines that would restrict access to care.[101] CMS solicited comment on the definition of widely used treatment guidelines and clinical literature that would justify internal coverage criteria used in the absence of NCDs, LCDs, or Traditional Medicare statutes or regulations along with the other requirements proposed in new § 422.101(b)(6)

b. Medical Necessity Determinations and Special Coverage Provisions

Per CMS regulations at § 422.112(a)(6)(ii), MA plans must have policies and procedures that allow for individual medical necessity determinations. As a result, an MA organization's coverage rules, practice guidelines, payment policies, and utilization management policies should be applied to make individual medical necessity determinations based on the individual circumstances for the enrollee and item or benefit to be covered. CMS has longstanding guidance interpreting the obligations of MA organizations when making medical necessity determinations. Chapter 4 of the MMCM, section 10.16, provides that MA organizations make coverage determinations that are based on: (1) the medical necessity of plan-covered services based on coverage policies (this includes coverage criteria no more restrictive than Traditional Medicare described previously and proposed at § 422.101(b)(6)); (2) where appropriate, involvement of the plan's medical director per § 422.562(a)(4); and (3) the enrollee's medical history (for example, diagnoses, conditions, functional status)), physician recommendations, and clinical notes. We proposed to codify these existing standards for medical necessity decision-making at § 422.101(c)(1)(i) and proposed some new requirements to connect medical necessity determinations to our new requirements at § 422.101(b). Therefore, as previously discussed, we

[101](for example, Oxford Centre for Evidence-Based Medicine levels of evidence https://www.cebm.ox.ac.uk/resources/levels-of-evidence/oxford-centre-for-evidence-based-medicine-levels-of-evidence-march-2009 and Strength of Recommendation Taxonomy https://www.jabfm.org/content/17/1/59#F1)

proposed to codify at § 422.101(c)(1)(i)(A) that MA organizations must make medical necessity determinations based on coverage and benefit criteria as defined at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria not found in those sources. Second, we proposed at § 422.101(c)(1)(i)(B) to require MA organizations to consider whether the item or service is reasonable and necessary under 1862(a)(1) of the Act. We note that this has been a longstanding policy in MA based on how section 1852 of the Act requires MA plans to cover items and services for which benefits are available under original Medicare, however, we believe it is important to acknowledge this in the context of MA organization decisions involving medical necessity. Third, we proposed to codify existing policy at § 422.101(c)(1)(i)(C) that MA organizations consider the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes. Finally, consistent with current requirements at § 422.562(a)(4), we proposed at § 422.101(c)(1)(i)(D) that MA organizations' medical directors be involved in ensuring the clinical accuracy of medical necessity decisions where appropriate. We solicited comments on when it would be appropriate for the MA organization's medical director to be involved, in light of how § 422.562(a)(4) requires the medical director to be responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity.

Authority for MA organizations to use utilization management policies with regard to basic benefits is subject to the mandate in section 1852(a)(1) of the Act that MA plans cover Medicare Part A and Part B benefits (subject to specific, limited statutory exclusions) and, thus, to CMS's authority under section 1856(b) of the Act to adopt standards to carry out the MA provisions. We believe these proposals will further implement the requirements set forth in section 1852 of the Act and §§ 422.100 and 422.101, which require MA organizations to furnish all reasonable and necessary Part A and B benefits. These requirements for how MA organizations make coverage decisions will ensure that MA organizations provide equal access to Part A and Part B benefits as provided in the Traditional Medicare program; overall these

mean that MA organizations will not be able to deny coverage for basic benefits using coverage criteria that is not consistent with coverage criteria in Medicare statutes, regulations, NCDs and LCDs or that is not consistent with the limitations proposed in § 422.101(b)(6).

In explaining the proposals in the proposed rule, we affirmed that coordinated care plans may continue to include mechanisms to control utilization, such as prior authorization, referrals from a gatekeeper for an enrollee to receive services within the plan, and, subject to the rules on physician incentive plans at §§ 422.208 and 422.210, financial arrangements that offer incentives to providers to furnish high quality and cost-effective care in addition to the coverage criteria that comply with § 422.101(b). We also affirmed that MA organizations may furnish a given service using a defined network of providers, some of whom may not see patients in Traditional Medicare, under these proposals. Further, we affirmed that MA organizations may encourage patients to see more cost-effective provider types than would be the typical pattern in Traditional Medicare (as long as those providers are working within the scope of practice for which they are licensed to provide care and comply with the provider antidiscrimination rules set forth under § 422.205). For instance, MA organizations may offer more favorable cost sharing for certain provider types within their network. We remind MA organizations that any incentives offered to providers and to patients must comply with applicable fraud and abuse laws.

In the proposed rule, we acknowledged in the June 2000 final rule that when a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, that an MA plan could choose how the covered services will be provided. We proposed a narrower policy that permits MA organizations to continue to choose who provides Part A and Part B benefits through the creation of their contracted networks, but limits MA organizations' ability to limit when and how covered benefits are furnished when Traditional Medicare will cover different provider types or settings. We explained that under our proposal at § 422.101(c)(1)(i), when care can be delivered in more than one way or in more than one type of setting, and a contracted provider has ordered or requested Medicare covered items

or services for an MA enrollee, the MA organization may only deny coverage of the services or setting on the basis of the ordered services failing to meet the criteria outlined in § 422.101(c)(1)(i). (We proposed to reserve paragraph (c)(1)(ii) to provide flexibility in modifying the limits on MA medical necessity policies in the future.) For example, if an MA patient is being discharged from an acute care hospital and the attending physician orders post-acute care at a SNF because the patient requires skilled nursing care on a daily basis in an institutional setting, the MA organization cannot deny coverage for the SNF care and redirect the patient to home health care services unless the patient does not meet the coverage criteria required for SNF care in §§ 409.30-409.36 and proposed § 422.101(b) and (c).

We explained that we were unable to quantify the impact of these proposed changes on MA organizations because many MA organizations may already be interpreting our current rules in a way that aligns with what we proposed. MA organizations may have interpreted our longstanding policy that they cannot apply coverage criteria that are more restrictive than Traditional Medicare national and local coverage policies to mean exactly what we proposed here: that they may only deny Medicare items or services based on criteria consistent with Traditional Medicare coverage rules. Other MA organizations may have interpreted our current rules to mean that they can use internal policies, like utilization management guidelines, to deny approval for a particular item or service while directing the MA enrollee to a different, but clinically appropriate, Medicare-covered item or service. The OIG stated in their report that "CMS guidance is not sufficiently detailed to determine whether MA organizations may deny authorization based on internal MA organization clinical criteria that go beyond Medicare coverage rules." As a result, we proposed to be clear that MA organizations may not deny authorization based on internal MA organization clinical criteria that go beyond Medicare coverage rules or do not comply with proposed § 422.101(b)(6) addressing standards for when MA internal coverage rules are permissible. However, we were unable to quantify or predict

how many MA organizations are currently operating in a manner that conforms with what we proposed. We solicited comment from stakeholders on the full scope of this burden.

We thank commenters for helping inform CMS's policy on coverage criteria for basic benefits in MA. We summarized comments in this section of this rule and our responses follow.

Comment: We received several comments thanking CMS for reiterating that MA plans must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans, and for clarifying that this includes coverage criteria for inpatient admissions at 42 CFR § 412.3, requirements for coverage of Skilled Nursing Facility Care and Home Health Services under Part 409, and Inpatient Rehabilitation Facilities coverage criteria at § 412.622(a)(3). Several commenters requested that CMS more clearly state that the proposed revisions to 422.101(b)(2) mean that MA plans must follow the Inpatient Only (IPO) list as well as the "two-midnight rule" presumption and benchmark for hospital inpatient admissions. Some commenters also requested that CMS more explicitly state that additional coverage criteria are prohibited when the IPO list and two-midnight rule are applicable. One commenter requested that CMS explicitly state that MA plans are prohibited from making medical necessity decisions based only on the duration of a hospital stay. Another commenter requested CMS clarify if plan adherence to § 412.3 still allows case management review of inpatient admissions based on whether the complex medical factors documented in the medical record support medical necessity of the inpatient admission, regardless of the actual duration of the hospital stay. Finally, some commenters asserted that requiring MA plans to follow the two-midnight rule as applied in Traditional Medicare, which includes the two-midnight presumption and benchmark, would violate non-interference rules at 422.256(a)(2)(ii) that preclude CMS from interfering in payment rates agreed to by an MA plan and its contracted providers. Additionally, these commenters stated that the requirements at § 412.3 are payment rules and not coverage rules.

Response: We thank commenters for their comments. In our proposal at 422.101(b)(2), we stated that MA plans must comply with general coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. We also stated that this includes coverage criteria for inpatient admissions at 42 CFR 412.3, requirements for coverage of Skilled Nursing Facility Care and Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities coverage criteria at 42 CFR 412.622(a)(3). We affirm here that the criteria listed at those regulations are applicable in MA.

MA organizations are required by Section 1852(a) to provide Part A or Part B items and services (with limited exceptions) through providers that have a contract with the MA organization or by payment to a provider that does not have a contract with the MA organization. CMS has interpreted those obligations in § 422.101(a) to require MA organizations to "provide coverage of, by furnishing, arranging for, or making payment for" these Part A or Part B items and services. Therefore, the distinctions between regulations that contain coverage criteria and regulations that contain criteria for Medicare payment in Traditional Medicare are not similarly applicable in the MA program because MA organizations provide coverage by furnishing, arranging for, or making payment for Part A and Part B items and services. As a result, when determining whether Traditional Medicare criteria apply in MA, it is irrelevant whether Traditional Medicare considers the criteria part of a coverage rule or a payment rule, as both address the scope items and services for which benefits are available to Medicare beneficiaries under Parts A and B. MA organizations have discretion about how much and under what conditions they pay their contracted providers that furnish services, but § 422.101(a) and (b) are about ensuring that MA enrollees receive the same items and services they would receive if they were enrolled in Traditional Medicare. We explain here what the new rule means and how it works using examples of Traditional Medicare criteria listed at § 422.101(b)(2) of this final rule.

In regards to inpatient admissions at 412.3, we confirm that the criteria listed at 412.3(a)-(d) apply to MA. We acknowledge that 412.3 is a payment rule for Medicare FFS, however,

providing payment for an item or service is one way that MA organizations provide coverage for benefits. Therefore, under § 422.101(b)(2), an MA plan must provide coverage, by furnishing, arranging for, or paying for an inpatient admission when, based on consideration of complex medical factors documented in the medical record, the admitting physician expects the patient to require hospital care that crosses two-midnights (§ 412.3(d)(1), the "two midnight benchmark"); when admitting physician does not expect the patient to require care that crosses two-midnights, but determines, based on complex medical factors documented in the medical record that inpatient care is nonetheless necessary (§ 412.3(d)(3), the "case-by-case exception"); and when inpatient admission is for a surgical procedure specified by Medicare as inpatient only (§ 412.3(d)(2)). However, it is important to clarify that the "two-midnight presumption" (the presumption that all inpatient claims that cross two midnights following the inpatient admission order are "presumed" appropriate for payment and are not the focus of medical review absent other evidence) does not apply to MA plans. The two-midnight presumption is a medical review instruction given to Medicare contractors (for example, MACs, RACs, QIOs) to help them in the selection of claims for medical necessity review. CMS guidance[102] states that Medicare contractors will presume hospital stays spanning two or more midnights after the beneficiary is formally admitted as an inpatient are reasonable and necessary for Part A payment. Under this presumption, Medicare contractors will generally not focus their medical review efforts on stays spanning two or more midnights after formal inpatient admission.

However, this final rule does not dictate how MA organizations will decide which claims to subject to review. Section 1852(g)(1)(A) of the Act states that an MA organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan is entitled to receive a health service and that such determinations regarding whether or not an individual may receive a health service must be made on a timely basis. CMS has adopted

[102]https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10080.pdf

regulations governing certain minimum procedures that MA plans must use, including the timing of organization determinations, the content of denial notices, and who must review a decision that the plan expects to be a full or partial denial on the basis of medical necessity before the denial can be issued. (See also section III.G. of this rule regarding the proposal to amend §§ 422.566(d) and 433.629(k) on this last point.) In addition, the regulations in part 422, subpart M address when and why an MA organization may reopen an organization determination at § 422.616, which incorporates the reopening regulations at §§ 405.980 through 405.986. However, CMS has not established requirements or limits on how MA organizations prioritize medical claims for review akin to the instructions CMS issues to Traditional Medicare contractors. Therefore, CMS instructions to Traditional Medicare contractors regarding how to prioritize medical claim review do not apply to MA organizations, under our interpretation. Accordingly, the amendments to § 422.101(b)(2) finalized here do not include any requirement for how MA organizations select inpatient admission claims for review, but we do confirm that the criteria listed at 412.3(a)-(d) apply. We confirm that MA plans may still use prior authorization or concurrent case management review of inpatient admissions based on whether the complex medical factors documented in the medical record support medical necessity of the inpatient admission, under either the two-midnight benchmark or the case-by-case exception.

Further, we do not believe that § 422.101(b), as finalized with our clarification about how 42 CFR 412.3 applies in the context of MA, violates the non-interference rule at section 1854(a)(6)(iii). We affirm MA organizations' rights to contract with providers of their choosing and to set the price structures, including how and how much contracted providers are paid. In addition, under the rules finalized here, MA organizations may adopt procedures, and in those situations specified in § 422.101(b)(6), internal coverage policies for making medical necessity determinations regarding whether an individual is entitled to receive a health care service under Part A or Part B, so long as the requirements and conditions set forth in the regulations are met. Our focus of this policy is not on how or how much MA organizations pay their contracted

providers, but on ensuring that MA enrollees receive items and services for which benefits are available under Part A and Part B (excluding hospice care and organ acquisitions for kidney transplants) that they would receive under Traditional Medicare.

We clarify here and amend the regulation text at § 422.101(b)(2) to state the applicability of the Inpatient Only list in MA, which, under § 419.22(n) are those services and procedures that the Secretary designates as requiring inpatient care and for which payment is not made when furnished in a hospital outpatient department under the Medicare Hospital Outpatient Prospective Payment System. We confirm that the Inpatient Only list applies to MA consistent with our read of the statute that when Traditional Medicare pays for a service only when certain conditions are met, meaning that those certain conditions must be met for the service to be considered a Traditional Medicare basic benefit, these same conditions, including setting, must be met in order for the service to be considered part of the basic benefit of an MA plan. As previously stated in this rule and in the proposed rule, if Traditional Medicare covers a service only when certain conditions are met, these conditions must be met in order for the service to be considered part of the Traditional Medicare benefits that must be included as basic benefits covered by an MA plan. Also, we remind MA plans that they may cover the same service when the conditions are not met—such as in a different setting or from a different type of provider — as a supplemental benefit. The regulation at § 412.3(d)(2) provides that an inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) is generally appropriate for payment under Medicare Part A regardless of the expected duration of care. Therefore, coverage of the inpatient admission for a procedure on the inpatient only list is fully established under the applicable Medicare regulations and the MA plan must cover this type of inpatient admission without application of additional internal criteria under new § 422.101(b)(6).

Comment: Many commenters expressed concern that the proposed rule limits MA plans' ability to adequately assess whether a covered item or service is medically necessary. Some commenters expressed concerns that Medicare coverage guidelines are not specific enough to be

relied upon to make medical necessity determinations. One commenter suggested that CMS provide additional clarity regarding what plans should do when there are no CMS guidelines applicable to a service and to provide examples regarding what is permissible under these circumstances. Similarly, one commenter recommended that CMS provide additional clarity on what a plan must do when an NCD or LCD acknowledges that additional coverage criteria may be applied to determine medical necessity. Another commenter requested that CMS establish a process that allows plans to ask CMS questions and request clarity on Medicare guidelines, including the applicability of certain guidelines. One commenter noted that CMS allows Medicare review contractors to use evidence-based guidelines to assist reviewers in making medical necessity determinations consistent with Traditional Medicare and requirements and, as such, MA plans should be able to maintain this ability.

Response: We thank commenters for their comments and we believe that "Medicare review contractors" used in this context means MACs in Traditional Medicare. We understand that Traditional Medicare statutes, regulations, NCDs, and LCDs do not always contain specific criteria for making medical necessity determinations in every situation for every applicable Part A or B service. Thus, in the proposed rule, we stated that when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, MA plans may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. We agree with commenters that in order to adequately adhere to this requirement, MA plans need additional clarity on what it means for Traditional Medicare coverage criteria to not be "fully established", and thus allowed to apply internal coverage criteria based on current evidence in widely used treatment guidelines or clinical literature. Based on commenter recommendations, and in order to more explicitly state the circumstances under which MA organizations may apply internal coverage criteria, we are finalizing § 422.101(b)(6) with additional modifications compared to the proposed version. We are finalizing a new paragraph (b)(6)(i) to explain in regulation text when coverage criteria are

not fully established. At § 422.101(b)(6)(i)(A)-(C) we explain that coverage criteria are not fully established when additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently; 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 there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria. This means that when any of these three circumstances are present, MA plans may develop and rely upon internal coverage criteria to make medical necessity decisions.

We agree with commenters that medical conditions and a patient's medical history can be complex and that Medicare coverage guidelines are not specific enough to address every possible scenario when benefits are available under Medicare Parts A or B for every item or service. We also acknowledge, as commenters stated, that MACs are permitted to consider evidence-based guidelines when making individual medical necessity determinations. Based on these comments, and in order to clarify when Traditional Medicare coverage criteria are not fully established, this final rule will permit MA organizations to adopt publicly accessible internal coverage criteria based on current evidence in widely used treatment guidelines when additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. First, we proposed and address in more detail in the following pages how, in addition to basing internal coverage criteria on current evidence in widely established treatment guidelines, MA organizations must follow certain procedures. Second, as specified at § 422.101(b)(6)(i)(A), 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. We will use this interpretation in monitoring and evaluating compliance with this regulation. We also require in this rule that MA organizations make this explanation publicly accessible, along with the internal coverage criteria in use, and

identify the general provisions that the internal coverage criteria supplement so that general provisions can be applied in specific factual circumstances.

We explained in the proposed rule, that in some circumstances, NCDs or LCDs expressly include flexibility that allows coverage in circumstances beyond the specific coverage or non-coverage indications that are listed in the NCD or LCD. We also acknowledged in the proposed rule that there are some Part A or Part B benefits that do not have applicable Medicare NCDs, LCDs, or specific traditional Medicare coverage criteria in regulation for MA plans to follow when making medical necessity determinations. Commenters agreed with these statements, and therefore, we are finalizing in the regulation text at § 422.101(b)(6)(i)(B) and (C) that coverage criteria are not fully established when 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 when there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria. When identifying whether there is an absence of applicable Medicare statutes, regulations, NCDs, or LCDs, the MA organization needs to look beyond the labels of "payment rule" or "coverage rule", as both serve to establish coverage criteria in MA. Therefore, this rule prohibits MA organizations from applying internal coverage criteria in addition to the applicable Traditional Medicare statutes, regulations, NCDs, or LCDs, unless § 422,101(b)(6)(i)(A) or (B) apply.

As part of applying and complying with § 422.101(b)(6), we expect that MA plans will consult the Medicare Benefit Policy Manual, Medicare Program Integrity Manual, and similar CMS guidance materials. These manuals contain significant explanations and interpretations of Traditional Medicare laws governing Part A and Part B benefits, most of it longstanding, to provide instructions and procedures for day to day operations for those responsible for administering the Medicare program and for making coverage decisions. Using these resources will ensure that MA plans are covering items and services for which benefits are available under Part A and Part B for their enrollees and minimize the number of potential situations where

Traditional Medicare coverage policies have insufficient detail such that an MA plan must develop its own internal coverage criteria.

When MA plans are permitted to adopt such internal criteria, however, it must be based on current evidence in widely used treatment guidelines or clinical literature and made publicly available. We believe that permitting the use of publicly accessible internal coverage criteria in these limited circumstances and contexts is necessary to promote transparent, and evidence-based clinical decisions by MA plans that are consistent with Traditional Medicare. We do not view the use of internal coverage criteria in these instances as being more restrictive than, or applying additional criteria beyond, Traditional Medicare because that is precisely what is contemplated, for example, by the NCDs or LCDs that provide for this type of flexibility and interpretation in Traditional Medicare. Use of internal policies based on current evidence in widely used treatment guidelines or clinical literature is appropriate to fill in gaps where coverage criteria cannot specify all possible circumstances where coverage of a Part A or Part B item or service may be available for a beneficiary. These policies provide MA organizations with limited discretion to interpret Traditional Medicare coverage rules and must not create barriers to access to care in a way that is not aligned with access in Traditional Medicare.

In order to demonstrate how this rule applies, we discuss an example of an actual coverage policy to further elucidate the limited circumstances under which MA plans may apply internal coverage criteria to supplement the existing coverage guidelines. First, in NCD 220.1 for Computed Tomography (CT)[103], the NCD states that, "[s]ufficient information must be provided with claims to differentiate CT scans from other radiology services and to make coverage determinations. Carefully review claims to ensure that a scan is reasonable and necessary for the individual patient; that is, the use must be found to be medically appropriate considering the patient's symptoms and preliminary diagnosis." Here, the NCD recognizes that individual circumstances are relevant in determining appropriate coverage, so the policy used the

[103]https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=176

term “sufficient” in order for the medical necessity reviewer to make a more accurate coverage determination. Additionally, the NCD allows the MAC medical staff to make an individual case determination that use of a CT scan as the initial diagnostic test was not reasonable and necessary because it was not supported by the patient’s symptoms or complaints stated on the claims form. In this circumstance, the MA plan would be allowed to apply current evidence in widely used treatment guidelines or clinical literature that is made publicly available, as defined at § 422.101(b)(6), to make consistent determinations about when it would be reasonable and necessary for the individual patient and what type of information is required to be submitted on the claim. The MA organization would need to demonstrate in its public explanation of the rationale that supports the internal coverage criteria 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. The MA organization would also need to identify the general provisions that are being interpreted or supplemented. In this case, the MA organization may use internal coverage criteria to further establish what “sufficient information” must be provided with the claim or pre-service request for coverage (including a prior authorization request).

In another example, NCD 220.2 for Magnetic Resonance Imaging (MRI)[104], the NCD lists indications and limitations of coverage as well as the contraindications and other non-covered indications for appropriate use of an MRI. However, it also provides for coverage under a category of “other” when “[a]ll other uses of MRI or MRA for which CMS has not specifically indicated coverage or non-coverage continue to be eligible for coverage through individual local MAC discretion.” Here, the NCD explicitly includes flexibility that allows for coverage in circumstances beyond the specific indications that are listed in an NCD and gives the medical necessity reviewer discretion to make this judgment. In order to make consistent determinations

[104]https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=177

on coverage in these "other" circumstances not specifically addressed by the NCD, § 422.106(b) as finalized permits an MA plan to adopt an internal coverage policy based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available.

We proposed at 422.101(c)(1) that MA organizations must make medical necessity determinations based on a number of factors, including the criteria in § 422.101(b), the enrollee's medical history, and other factors. Thus, to the extent that an MA organization has developed internal coverage criteria as permitted by § 422.101(b)(6) (including compliance with the procedures set forth in paragraphs (b)(6)(i) through (ii)), the current evidence in widely used treatment guidelines or clinical literature that are the basis for the internal coverage policy should also be used in making individual medical necessity determinations. Therefore, MA organizations may use these internal criteria to deny coverage of an item or service. However, as required by § 422.568 and 422.631 (for applicable integrated plans), MA organizations must give enrollees written notice of a denial and the notice must state the specific reasons for the denial. We clarify here that if an MA organization denies care based on internal criteria, that criteria must be clearly stated in the denial notice, just as other applicable Medicare coverage criteria must be stated under § 422.568(e)(2), when used as the basis for a denial of coverage. Communicating all necessary information needed for the enrollee or provider to effectively appeal the decision, including the evidence used to support the internal coverage policy when applicable, is one of the purposes of the denial notice. The standardized Integrated Denial Notice is properly completed when it includes a specific and detailed explanation of why the medical services, items or Part B drugs were denied, including a description of the applicable coverage rule or applicable plan policy (for example, Evidence of Coverage provision) upon which the action was based, and a specific explanation about what information is needed to approve coverage must be included, if applicable.

In light of the issues raised by commenters, we are finalizing 422.101(b) with modifications to clarify when Traditional Medicare coverage criteria are not fully established and

what information about internal coverage criteria must be made publicly accessible. We will continue to conduct audit and monitoring activities to ensure that appropriate coverage criteria are applied during medical necessity reviews, and if CMS identifies abuses of this policy, we will consider future rulemaking on this topic.

Comment: We received several comments asking CMS to prohibit use of commercial and proprietary criteria by MA plans. Many commenters stated that MA plan coverage criteria are often inconsistent, outside the scope of reasonable standards of practice, and more restrictive than Traditional Medicare guidelines. Some commenters requested that CMS not prohibit use of proprietary coverage criteria and tools, such as InterQual or MCG systems, stating that that these tools help plans consolidate Medicare regulations and assist plans in making evidence-based, clinically appropriate medical necessity determinations. Another commenter requested that CMS continue to allow plans to use independent third-party, proprietary tools to guide medical necessity determinations.

Response: We thank commenters for expressing their concerns. However, use of these tools, in isolation, without compliance with requirements in this final rule at § 422.101(b), (c), and § 422.566(d), is prohibited.

We understand that utilization management tools such as InterQual or MCG, among others, are coverage criteria products created to assist the plans, providers and others, in clinical review processes and to help guide medical necessity determinations. We understand from commenters that these products were created with the intention of serving as a single source that consolidates clinical data, medical literature, and CMS guidance and coverage policies to assist MA plans in making medical necessity determinations. We understand from commenters that these tools are often used in conducting inpatient, post-acute and home care medical necessity reviews, in particular.

As finalized, §§ 422.101(b), (c) and 422.566(d) address different aspects of how these products appear to be used so consideration of all three regulations is necessary. As proposed and

finalized in § 422.101(b)(2), MA plans must comply with 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, such as 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)). Thus, MA plans may not use InterQual or MCG criteria, or similar products, to change coverage or payment criteria already established under Traditional Medicare laws.

We recognize that there are some Part A or Part B benefits that do not have applicable Medicare NCDs, LCDs, or specific traditional Medicare coverage criteria in regulation for MA plans to follow when making medical necessity determinations. Therefore, we proposed at § 422.101(b)(6) that when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. In creating these internal policies, we proposed that MA organizations must follow rules similar to those CMS and MACs follow when creating NCDs or LCDs. Specifically, MA organizations must provide publicly available information that discusses the factors the MA organization considered in making coverage criteria for medical necessity determinations.

Under this final rule, when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD, MA plans may create internal coverage criteria under specific circumstances described at § 422,101(b)(6)(i). In these circumstances, an MA plan is permitted to choose to use a product, such as InterQual or MCG or something similar, to assist in creating internal coverage criteria only so long as the requirements in § 422.101(b), (c), and § 422.566(d) are met. Specifically, MA plans must comply with § 422.101(b) and (c) as to: (i)

what coverage criteria are applied; (ii) how, if those criteria are not only from Medicare laws, NCDs or LCDs, the coverage criteria were developed and what they are based on, and (iii) how individualized determinations of medical necessity take into account the information and considerations specified in § 422.101(c)(1). In addition, if the organization determination made using the product is expected to be a full or partial denial, the MA plan must ensure that the additional review requirements in § 422.566(d) are met. (See section III.G of this final rule.) The MA plan must therefore ensure that the coverage criteria used in these products are based on current evidence in widely used treatment guidelines and clinical literature consistent with the definitions and standards in § 422.101(b)(6) before using the product as the MA plan's internal coverage policy. Further, MA organizations must comply with specific procedures, which we discuss in more depth later in this preamble, before an internal coverage policy – including a product such as those described by the commenters - may be used; the MA plan must provide, in a publicly accessible way, the internal coverage criteria in use; a summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations; a list of the sources of such evidence; and an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. This includes, when applicable, how the additional criteria interpret or supplement general provisions in Traditional Medicare and provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. MA organizations must ensure that they are making medical necessity determinations based on the circumstances of the specific individual, as outlined at § 422.101(c), as opposed to using an algorithm or software that doesn't account for an individual's circumstances. Finally, MA organizations must comply with amended § 422.566(d), as in section III.G of this final rule, which requires that a denial based on a medical necessity determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the service at issue.

We understand from commenters that many of these products and their software are proprietary in nature and may be proprietary to the particular organization that uses these products. However, use of such tools and their proprietary nature does not absolve MA plans from their responsibilities under this final rule. For an MA plan to use the coverage criteria in these tools, the MA plan will need to understand the external clinical evidence relied upon in these products and how that evidence supports the coverage criteria applied by these tools. The MA plan must make the evidence that supports the internal criteria used by (or used in developing) these tools publicly available, along with the internal coverage policies themselves. Furthermore, under § 422.504, MA organizations must provide information and access to CMS (and HHS and the OIG) as it conducts its oversight of MA plans and their compliance with MA program requirements. CMS may, therefore, review all aspects of the plan's decision-making including whatever evidence might be contained within a decision tool, or support the determinations made from the use of decision tool, including such tools provided by third-parties as discussed here. We expect MA plans already using these tools, or those that may plan to use these tools in the future, to work with third parties that provide these tools to revise any utilization management products and ensure that these products meet the requirements at § 422.101(b), (c), and § 422.566(d).

Comment: Several commenters expressed concern that requiring MA plans to strictly adhere to Traditional Medicare coverage policies undermines MA plans' ability to appropriately manage care. Commenters stated that adhering to Traditional Medicare coverage policies will impede a plan's ability to make medical necessity decisions. Commenters also stated that the proposed policies would restrict a plan's ability to direct patients to clinically-equivalent, lower-cost alternative treatments or therapies first. Several commenters warned that our proposal could lead to increased costs and duplicative and unnecessary services. Several commenters stated that our proposal will undermine the transition to value-based care and similar payment models. Some commenters expressed concern that adherence to 42 CFR § 412.3, part 409, and § 412.622

will remove the existing flexibility of MA plans to provide the same level of care in different settings. One commenter stated that removing the flexibility for plans to provide care in alternate settings could shift care from beneficiary homes to institutional settings, resulting in increased costs for both the plans and beneficiaries. For example, one commenter expressed concern that Traditional Medicare Skilled Nursing Facility payment rules in particular incentivize facilities to prolong Skilled Nursing Facility stays regardless of patient need.

Response: We proposed to codify at § 422.101(c)(1)(A) that MA organizations must make medical necessity determinations based on coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria that are not specified in § 422.101(b) or (c). This means that when an MA organization is making a coverage determination on a Medicare covered item or service and that item or service has fully established coverage criteria, the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies. However, this rule does not mean that an MA organization must deny coverage of all other treatment alternatives for an MA enrollee. MA plans may have supplemental benefits that cover of items and services that are not covered under Parts A or B. In addition, where Traditional Medicare would cover services in specific or various settings or from specific or various providers or cover alternative services or treatment options for the beneficiary, an MA organization must also cover those as basic benefits. An MA plan may make its enrollees aware of other covered treatment options or encourage specific treatment options as part of the MA plan's coordination and management of care for enrollees. We reiterate that when an item or service has fully established coverage criteria under Traditional Medicare, use by an MA plan of certain utilization management processes, such as clinical treatment guidelines that require another item or service be furnished prior to receiving the requested item or service, violate the requirements proposed, and being finalized in this rule, at § 422.101(b) and (c). Utilization management processes that are specified within the applicable NCD or LCD or

Medicare statute or regulation are permissible. By contrast, when coverage criteria are not fully established and MA organizations are allowed to adopt internal coverage criteria based on current evidence in widely used treatment guidelines or clinical literature, clinical treatment guidelines that require another item or service to be furnished prior to receiving the requested item or service must be expressly cited in the evidence in order for it to be acceptable under our rule. Clinical criteria that restrict access to a Medicare covered item or service, unless another item or service is furnished first, are not based on current evidence if the evidence does not cite or discuss the use of a different item or service first. When not specifically required in a Medicare law, NCD or LCD or part of the clinical evidence that supports an internal coverage policy that is permitted because Traditional Medicare coverage criteria are not fully established, use of a "try first" or similar utilization management process would be additional internal coverage criteria prohibited by § 422.101(b)(6) as finalized in this rule. We believe this policy provides enough flexibility for MA organizations to manage care so long as that management is grounded in current evidence in widely used treatment guidelines or clinical literature and made publicly available. Use of this flexibility by MA organizations is only allowed when coverage criteria are not fully established in applicable Medicare statute, regulation, NCD or LCD as stated at § 422.101(b)(6)(i).

Comment: Some commenters also expressed concern about the appropriateness of Traditional Medicare coverage guidelines. These commenters suggested that these guidelines may need to be updated and are not in line with current medical standards.

Response: NCDs are made and updated through an evidence-based process, with opportunities for public participation through a public comment and review process. NCDs are updated through CMS-generated reviews and through requests by an external party for a new NCD, for reconsideration of an existing NCD, or by an aggrieved party to issue an NCD when no NCD exists as established in Final Notice 78 FR 48164 in 2013. CMS makes proposed NCD decisions available on the CMS website for a 30-day public comment period after which

comments are reviewed and a final decision is issued not later than 60 days after the conclusion of the comment period. A summary of the public comments received and responses to the comments are included in the decision memorandum. In some cases, CMS's own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). When developing LCDs, MACs use published, original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines. Further, LCDs undergo a similar process to that for NCDs, including public participation. Because Traditional Medicare follows a process of expert consultation and public review and comment in order to stay up-to-date and align with current medical standards and practices as it develops the coverage guidelines governing Traditional Medicare's basic benefits, we believe that these processes are sufficient in creating appropriate coverage guidelines.

Comment: Some commenters noted that the proposed language at § 422.101(b)(2) no longer includes a reference to complying with original Medicare manuals and instructions. Some commenters noted that manual guidance often includes necessary coverage guidance not included in Medicare regulations. These commenters requested that CMS maintain compliance with manual guidance at § 422.101(b)(2).

Response: We thank commenters for their observations. Section 422.101(b)(2), with the proposed revisions (which we are finalizing with modifications) references Traditional Medicare laws and existing § 422.101(b)(1) and (b)(3) require compliance by MA plans with NCDs and LCDs based on how section 1852(a)(2)(C) and (a)(5) of the Act make clear that MA plans must cover benefits consistent with NCDs and LCDs. Although § 422.101(b) will no longer refer to "original Medicare manuals and instructions," those materials are invaluable in interpreting and understanding the scope of Part A and Part B benefits and what benefits are available under Parts A and B in order to determine what Traditional Medicare covers in specific situations. Substantive legal standards about Medicare benefits may be established through rulemaking and

NCDs. In revising § 422.101(b)(2) to refer to Traditional Medicare regulations and statutes, we are not diminishing the content and value that these manuals and instructions provide in interpreting and defining the scope of Part A and Part B benefits. These manuals contain significant explanations and interpretations of Traditional Medicare laws governing Part A and Part B benefits, most of it longstanding, to provide instructions and procedures for day-to-day operations for those responsible for administering the Medicare program and making coverage decisions on individual claims, so we expect that MA plans will consult the Medicare Benefit Policy Manual, Medicare Program Integrity Manual, and similar CMS guidance materials.

Comment: We received some comments requesting that CMS establish a minimum number of days of initial Inpatient Rehabilitation Facilities or Skilled Nursing Facility coverage.

Response: We thank commenters for their suggestion and note that the minimum scope of IRF and SNF benefits are statutory requirements under the Medicare statute. We did not propose a separate MA coverage requirement for initial Inpatient Rehabilitation Facilities or Skilled Nursing Facility coverage, nor did we propose to make changes to the structure of basic benefits covered under Parts A and B. Our proposal aims to align the applicable coverage criteria in MA with Traditional Medicare to ensure comparable coverage for beneficiaries across both programs. Therefore, we consider changes to scope or structure of Part A or B benefits outside of the scope of this rule.

Comment: Some commenters expressed concern about MA plans' ability to provide a summary of evidence for all services. One commenter stated that sources often lack evidence to support all types of care. Some commenters also requested that CMS clarify what exactly is meant by "summary of the evidence that was considered." These commenters requested that CMS clarify whether this includes a citation to an article or a comprehensive synthesis of each study used, stating that the latter would be time consuming and extremely burdensome. Other commenters requested CMS provide guidance on how this information should be shared publicly, noting that some resources may be behind a paywall. One commenter suggested that

plans be required to post this information in a visible location on their websites. A few commenters suggested that CMS also require MA plans to make any internal coverage criteria publicly available and that this information should be available at least 30 days prior to implementation. One commenter suggested CMS require MA plans to consult with up to date clinical databases if we determined that a full in-depth review of evidence was too burdensome. Another commenter requested that CMS require that a summary of evidence be provided upon request instead of publicly posted. One commenter requested that CMS clarify and provide examples of appropriate "widely used treatment guidelines." Some commenters stated that consideration should be given to quality of literature and not only how often it is used. Other commenters suggested that CMS should require that the draft coverage policy be available for review and public comment. Finally, some commenters expressed concern that there is not enough data or widely used treatment guidelines available on certain conditions, including rare diseases. Given these challenges, some commenters requested CMS provide plans with flexibility in meeting this requirement. One commenter expressed concern that the public summary of evidence would require significant time and administrative effort.

Response: We thank commenters for their comments. We proposed, and are finalizing at § 422.101(b)(6), that MA organization's internal clinical criteria must be based on current evidence in widely used treatment guidelines or clinical literature. In the proposed regulation text, we stated that 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. We provided an example by referring to the Infectious Diseases Society of America for the Treatment of *Clostridium Difficile*. We also explained that current, widely-used treatment guidelines include those used to determine appropriate level of care (such as the American Society of Addiction Medicine Criteria for placement, continued stay, and transfer or discharge of patients with addiction and co-occurring conditions). We proposed that clinical literature acceptable for use to justify internal coverage criteria 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. Evidence that is unpublished, is a case series or report, or derived solely from internal analyses within the MA organization, or that does not comply with the standards described in the regulation would not represent proper justification for instituting internal coverage guidelines that would restrict access to care. These types of evidence have not undergone peer-review, are not transparent, or are not research methodologies that can plausibly establish causality. This evidentiary standard is overall consistent with published frameworks that rank the reliability of different types of studies in the clinical literature.

With regards to requiring MA plans to have a review and comment process for their internal coverage criteria, we remind commenters that per CMS regulations at §422.202(b), MA organizations that use a network of providers (for example, coordinated care plans) have obligations with regard to developing and using practice guidelines and utilization management guidelines, including establishing a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures. We believe that the regulations at § 422.202(b) provide a formal and sufficient mechanism for MA organizations to receive comment from contracted providers on internal coverage criteria, instead of having a review and comment period open to the general public. Therefore, we proposed and are finalizing a revision to § 422.202(b)(1)(i) to require practice guidelines and utilization management guidelines used by an MA organization that uses a network of providers to base those guidelines on current evidence in widely used treatment guidelines or clinical literature. Additionally, existing requirements under § 422.202(b) require that MA plans' practice guidelines and utilization management guidelines must consider the needs of the enrolled population; be developed in consultation with contracting physicians; be

reviewed and updated periodically; and be communicated to providers and, as appropriate, to enrollees. Further, decisions with respect to utilization management, enrollee education, coverage of services and other areas in which the guidelines apply must be consistent with the guidelines. We believe that an additional requirement that plans go through a comment period is redundant of these existing requirements regarding provider participation and that no additional requirements along such lines are necessary.

At 87 FR 79501, we proposed that an MA organization provide a publicly accessible summary of the evidence considered in developing the internal coverage criteria, a list of the sources of evidence, and an explanation of the rationale for the internal coverage criteria in order to protect beneficiaries by ensuring that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature and to provide transparency. However, the regulation text at proposed § 422.101(b)(6)(i) through (iii) inadvertently limited the phrase "publicly accessible" to only the summary of evidence. We are finalizing the proposal with modifications to the regulation text to be consistent with the scope of the proposal described in the preamble. Additionally, we are renumbering these criteria to as (A) through (C) in newly established subparagraph (ii).

Along with the new standards being adopted at § 422.101(b)(6)(i)(A) to allow MA organizations to create internal coverage criteria when additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently, we also are enhancing transparency requirements at § 422.101(b)(6)(ii)(C). When an MA organization uses internal coverage criteria in accordance with § 422.101(b)(6)(i)(A), they must also include in their publicly accessible explanation of the rationale that supports the adoption of the coverage criteria, an identification of 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. For example, the evidence supporting use of an internal policy may

demonstrate that patients benefit from increased efficacy of treatment or increased patient safety and highly outweighs the potential for the criteria to be used as a barrier to care that delays or denies access to items or services. While we acknowledge that this new requirement in § 422.101(b)(6)(ii) will increase burden on MA organizations, we believe that the benefits of transparency in the development of internal coverage criteria balances out that burden. We note that MA organizations may cite to policies or publicly available evidence that is behind a paywall without having to provide access to the policy directly. The standard at § 422.101(b)(6) allows MA organizations to create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature; it does not require that the MA organization to provide direct access to the source, but they must make publicly available the information required at § 422.101(b)(6)(ii). This could be in the form of a written summary that summarizes the evidence and treatment guidelines or clinical literature and provides a link or citation to the location of the evidence. This transparency provides assurances that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature, which we believe will protect MA enrollees. In an effort to provide plans with flexibility, we decline to require specific mechanisms for how the information is made publicly available. However, we do recommend MA plans refer to the coverage criteria and summary of evidence presented by MACs as a guide and best practice for how to present this information publicly. We are finalizing § 422.101(b)(6)(ii) with modifications to make everything listed in paragraphs (b)(6)(i) through (iii) of the proposed rule publicly accessible and to enhance transparency requirements related to the use of internal coverage criteria.

Comment: Some commenters requested that CMS require MA plans to adhere to Traditional Medicare coding policies related to how MA organizations pay providers. Another commenter suggested CMS also require MA plans to use only CMS' software and billing processes.

Response: We thank commenters for their suggestions. We remind commenters that section 1854(a)(6)(B)(iii) of the Act and MA regulations at § 422.256(a)(2)(ii) expressly prohibit CMS from interfering in price structures agreed to by an MA plan and its contracted providers. Whether or how a MAO pays its providers for furnishing covered services through use of a particular CPT code or some other mechanism can vary depending on the contract between the MA plan and the provider. We note that while MA organizations can develop their own payment methodologies for in-network providers for different diagnoses or procedure codes, national standard code sets for ICD-10 codes and CPT/HCPCS codes, along with respective coding guidelines, as required under HIPAA, must be followed. In this sense, the code sets and associated coding guidelines used in Traditional Medicare are the same as those required to be used by MA organizations. Further, when submitting encounter data to CMS, MA organizations must comply with the data structure and coding vocabularies established by CMS for such data and MA encounter data must conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards. (See § 422.310(d)) For non-contract providers, section 1852(a)(2) requires MA organization to pay non-contracted providers what they would receive in the Traditional Medicare program (that is, the FFS program) for furnishing the Part A or Part B services. Because Traditional Medicare uses specific codes and payment procedures, when a non-contracted provider uses those codes to request payment from an MA organization, the MA organization may not deny payment on the basis that the codes that were submitted are not used by the MA organization and its contracted providers

Comment: With respect to medical necessity determinations, several commenters stated that plan medical directors often issue determinations without up to date patient data. These commenters suggested that CMS require that prior to issuing a medical necessity determination, the plan medical director must have direct access to all of the relevant information available to the plan and the responsibility to review all this information. Several commenters stated that

peer-to-peer reviews often include medical directors without relevant expertise. These commenters suggested CMS require plans to use a reviewing medical director who has specific expertise in the relevant areas.

Response: We thank commenters for their suggestions. We proposed, and are finalizing in this rule, at § 422.101(c)(1)(i)(C), that MA organizations must make medical necessity determinations based on, among other things, the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes. This regulation requirement means that the MA organization, and its staff that review requests for an organization determination related to medical necessity, must review these materials that are specific to the enrollee and the contemplated services. We do not believe that our regulation needs to require that MA plan medical directors have direct access to all of the relevant information available to the plan and the responsibility to review all this information before any medical necessity determinations are made. As proposed and finalized, § 422.101(c)(1)(D) requires involvement of the MA plan medical director where appropriate. Per § 422.562(a)(4), which has not been amended in this rule, MA plan medical directors are responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity. MA organizations must have adequate procedures and systems in place to fulfill their obligations under part 422, including making organization determinations about coverage. (See for example, §§ 422.503(a)(4) 422.504(a)(16) and 422.566(a)). Section 422.101(c)(1)(C) requires that medical necessity determinations be made based on, among other things, the enrollee's medical history, physician recommendations, and clinical notes. This effectively means that all relevant clinical information is to be used by the MA plan in making the determination. Also, we are also finalizing the proposal to revise §§ 422.566(d) and 422.629(k)(3), in section III.G of this rule, to state that the physician or other appropriate health care professional who conducts the organization determination review must have expertise in the field of medicine that is appropriate for the item or service being requested before the MA

organization or applicable integrated plan (AIP) issues an adverse decision on medical necessity. In response to the comment that that peer-to-peer reviews often include medical directors without relevant expertise, we interpret peer to peer review to mean a discussion between the patient's doctor and a medical professional at the MA plan to obtain a prior authorization approval or appeal a previously denied prior authorization. While CMS does not have requirements that govern who within an MA plan must conduct peer to peer reviews, we reiterate that if the MA plan issues an adverse organization determination, the physician or other appropriate health care professional who conducts the organization determination review must have expertise in the field of medicine that is appropriate for the item or service being requested.

Comment: Some commenters requested that CMS require that a treating clinician's medical determination be the primary factor in any determination related to admission or transfer to another level of care when no NCD or LCD is present.

Response: We thank commenters for their suggestions. Under the revisions to § 422.101(c)(1) that we proposed and are finalizing in this rule, physician recommendations are required to be considered when making medical necessity determinations about the specific enrollee and requested services. This will apply in all contexts, not only when an enrollee is being transferred from one level of care to another or being admitted on an inpatient basis. Specifically, CMS proposed to codify at 422.101(c) that MA organizations must make medical necessity determinations based on: 1) coverage and benefit criteria as specified or authorized at 422.101(b) and (c) (and may not deny coverage for basic benefits based on coverage criteria that are not specified in § 422.101(b) or (c); 2) whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act; 3) the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes; and 4) where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4). This regulation text is based on longstanding guidance in section 10.16 of Chapter 4 of the Medicare Managed Care Manual. In codifying this policy for medical necessity

determinations, we reiterate that these four factors are appropriate and necessary considerations when making a medical necessity determination.

Comment: One commenter requested CMS clarify whether the proposed rules around coverage criteria for basic benefits prevent plans from providing supplemental benefit based on functional or social determinants of health (SDOH) needs.

Response: The rules around coverage criteria for basic benefits adopted and discussed in this final rule do not prevent MA organizations from taking SDOH into account when designing or determining eligibility for Special Supplemental Benefits for the Chronically Ill (SSBCI) §422.102(f). For clarity, we remind the commenter that as discussed in the 2020 Final rule (85 FR 33796), MA plans may consider social determinants of health as one factor, when determining eligibility for an SSBCI, to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI. However, MA plans may not use social determinants of health as the sole basis for determining eligibility for SSBCI.

Comment: Some commenters requested that CMS clarify how we intend to enforce the requirements in section III. E of this rule, including the new requirements related to coverage criteria at § 422.101(b)(2) and § 422.101(b)(6) and medical necessity determinations at § 422.101(c). One commenter suggested CMS audit inpatient admissions to ensure the rules are followed.

Response: We thank commenters for their comments. As stated in the proposed rule, CMS currently monitors MA organization compliance with this existing policy through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations are designed to alert CMS to any issues with access to care, and CMS may require MA organizations to address these matters if they arise. CMS intends to continue these oversight operations to ensure MA organizations' compliance with the provisions in this final rule. Furthermore, as previously discussed, under § 422.504, MA organizations must provide information and access to CMS (and HHS and the OIG) as it conducts its oversight of MA plans

and their compliance with MA program requirements. CMS may, therefore, review all aspects of the plan's decision-making as necessary to ensure compliance with program rules.

Comment: We received some comments requesting that CMS delay the implementation date of the utilizations management related provisions in this rule, including the medical necessity proposals at § 422.101(b) and (c). One commenter stated that they were concerned that plans would have a limited time to review, assess, and implement changes needed to comply with these rules. Another commenter stated that compliance with these changes would require contracting, staffing, and resource infrastructure changes. Some commenters stated that providing a publicly accessible summary of evidence (considered during the development of the criteria) would require significant administrative effort in particular. Some commenters stated that the implementation date should be delayed because utilization management provisions finalized in this rule, would require significant administrative effort to implement.

Response: We thank commenters for expressing their concerns.. We believe MA organizations already have robust processes and systems in place for making medical necessity determinations, as these decisions are inherent in and fundamental to any care coordination plan. We acknowledge that compliance with § 422.101(b) and (c) will require changes to existing plan processes and create burden for MA organizations. We believe that many MA organizations are already following Traditional Medicare coverage guidelines, while others may be making greater use of other clinical decision-making tools that fall outside Traditional Medicare. As such, we are not able to fully quantify the burden of these changes. Nevertheless, we believe it is important to codify clearer rules regarding how Part A and B benefits must be covered and furnished in the MA program as soon as possible in order to ensure that all MA enrollees receive the basic benefits coverage to which they are entitled.

We solicited comment on the burden associated with our proposals. As discussed, we stated that we were unable to quantify or predict how many MA organizations are currently operating in a manner that would conform with our proposed changes to § 422.101(b) and (c).

We solicited comment from stakeholders on the full scope of this burden. As previously discussed, some commenters stated that the utilization management provisions and coverage criteria requirements in this rule would require significant administrative effort. For example, some commenters stated that providing a publicly accessible summary of evidence would require significant administrative effort. Some commenters asserted that the rules presented here would require changes to contracts, staff, resource infrastructure, and other plan related systems and processes. One commenter stated that CMS did not adequately account for the effort associated with meeting these requirements. However, we did not receive comments on our cost and burden analyses. The stakeholder comments of increased administrative burden are consistent with our statement in the proposed rule that due to its complexity and many unknowns, we cannot quantify the burden.

After careful consideration of all comments received, and for the reasons set forth in the final rule and in our responses to the related comments in sections III.E.2 of this final rule, we are finalizing the substance of our proposals for § 422.101(b) and (c) with modifications as follows:

- We are finalizing amendments to § 422.101(b)(2), largely as proposed but with modifications to clarify the scope of the requirement and to correct the citation to 42 CFR 412.622(a)(3) and to explicitly state the applicability of the inpatient only list.
- We are finalizing the regulatory language at § 422.101(b)(6) largely as proposed, but with modifications to state when coverage criteria are not fully established, to clarify that the obligation to make information publicly accessible applies to the internal criteria in use, to enhance transparency requirements related to use of internal coverage criteria. Based on the scope of these modifications and clarifications, we have slightly reorganized paragraph (b)(6) to add a new paragraph (b)(6)(i) to address when Medicare coverage criteria are not fully established and a new paragraph (b)(6)(ii) to address the

procedural and transparency requirements that apply when an MA organization adopts internal coverage criteria for basic benefits.

- We are finalizing the modifications at 422.101(c) as proposed; and
- We are finalizing the re-designation of *Exception for qualifying hospital stay* paragraph from 422.101(c)(1) to 422.101(c)(2) as proposed.

3. Appropriate Use of Prior Authorization

Except for emergency, urgently needed, and stabilization services (§ 422.113(a)), and out-of-network services covered by MA PPO plans, all services covered by MA coordinated care plans (including MSA network plans, which are coordinated care plans under 422.4(a)(iii)(D)), may be subject to prior authorization. In addition, MA PFFS and MA MSA plans 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 or MSA plan in advance that services will be furnished. See § 422.4(a)(2)(i)(B) and (a)(3)(iv). Appropriate prior authorization should only be used to confirm the presence of diagnoses or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically appropriate and should not function to delay or discourage care. Therefore, we proposed to codify this at new § 422.138(a). Specifically, we proposed a new § 422.138(a) to provide that a coordinated care plan may use prior authorization processes for basic benefits and supplemental benefits only when the prior authorization processes are consistent with new § 422.138. We explained that, for purposes of this proposal, we used the term "processes" to include prior authorization policies and procedures that address any and all aspects of how prior authorization is used by an MA organization in a coordinated care plan.

We also proposed a new § 422.138(b)(1) through (3) to limit the use of prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure basic benefits

are medically necessary based on standards specified in § 422.101(c)(1), or to ensure that the furnishing of supplemental benefits is clinically appropriate.

The standard "clinically appropriate" used for supplemental benefits is consistent with longstanding guidance in Chapter 4, section 30.2, of the MMCM (and also stated in the CY 2021 Final Rule [86 FR 5864]) that supplemental benefits must be medically necessary. Special Supplemental Benefits for the Chronically Ill (SSBCI) may be non-primarily health related so a standard based on medical necessity may not always be appropriate. Regular supplemental benefits must be medically necessary, but SSBCI need to have a reasonable expectation of improving or maintaining the health or overall function of the enrollee as required at § 422.102(f)(1)(ii) and discussed in CY 2020 Final Rule (85 FR 33796).

To illustrate how these proposed prior authorization policies would work, we discussed an example regarding coverage of acupuncture. Traditional Medicare currently has an NCD for Acupuncture for Chronic Lower Back Pain (cLBP).[105] This NCD authorizes acupuncture for Medicare patients with chronic Lower Back Pain (cLBP) for up to 12 visits in 90 days under the following circumstance: lasting 12 weeks or longer; nonspecific, in that it has no identifiable systemic cause (that is, not associated with metastatic, inflammatory, infectious disease, etc.); not associated with surgery; and not associated with pregnancy. Here, an MA plan may require prior authorization, before authorizing treatment as a covered basic benefit, to verify the patient's pain is not the result of metastatic, inflammatory, infectious disease, as specified in the NCD. In this example, the plan is using the prior authorization to confirm a diagnosis specified in appropriate Medicare Part B coverage policy (in this case an NCD). Hence, prior authorization is used in this case to confirm the appropriate use of clinical standards in order to verify that Traditional Medicare coverage criteria are met, thus ensuring appropriate care, which is acceptable. CMS guidance (section 10.16 of Chapter 4 of the MMCM) currently states that if the plan approved the furnishing of a service through an advance determination of coverage, it may

[99]https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=373

not deny coverage later on the basis of a lack of medical necessity. This means that when an enrollee or provider requests a pre-service determination and the plan approves this pre-service determination of coverage, the plan cannot later deny coverage or payment of this approval based on medical necessity. The only exception here would be medical necessity determinations for which the plan has the authority to reopen the decision for good cause or fraud or similar fault per the reopening provisions at § 422.616. This has been longstanding sub-regulatory guidance (section 10.16 of Chapter 4) that we proposed to codify at § 422.138(c) to ensure the reliability of an MA organization's pre-service medical necessity determination. Therefore, we did not believe there was any additional impact on MA organizations caused by the proposal to codify this at proposed § 422.138(c) and we solicited stakeholder input on the reasonableness of this assumption. We also solicited comment whether combining all of our proposals on prior authorization (here and in section III.E.4 of this proposed rule discussing proposed changes to § 422.112(b)(8)) in proposed new § 422.138 would make applying and understanding these requirements clearer for the public and MA organizations.

Finally, we also reminded MA plans that section 1852(b) of the Act states that an MA plan may not deny, limit, or condition the coverage or provision of benefits under this part, for individuals permitted to be enrolled with the organization under this part, based on any health status–related factor described in section 2702(a)(1) of the Public Health Service Act. Additionally, per CMS regulations at § 422.100(f)(2), plan benefit designs may not discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. We consider prior authorization processes to be part of the plan benefit design, and therefore such processes cannot be used to discriminate or direct enrollees away from certain types of services.

We explained that a complete estimation of impact from proposed § 422.138(a) and (b) cannot be given because we would need detailed knowledge of proprietary plan information on the frequency and specific services for which prior authorization is done in each plan. (As noted

in a prior paragraph, proposed § 422.138(c) would only codify existing guidance to MA organizations.) We solicited comment from stakeholders on the impact and any additional information that would assist CMS in making an estimation. Some commenters stated that publicly posting a summary of evidence considered during the development of the criteria would require significant administrative effort. However, we did not receive specific comments on our estimates. The stakeholder comments of increased administrative burden are consistent with our statements in the proposed rule, that due to its complexity and many unknowns we cannot quantify the burden. We thank commenters for helping inform CMS's policy on the appropriate use of prior authorization and the requirements proposed at § 422.138. We summarize the comments and our responses follow.

Comment: Some commenters asserted that this proposed rule goes against sections 1852(c)(1)(G) and (c)(2)(B) of the Act, and the MA regulations at § 422.4(a)(1)(ii) which reference a MA plan's application of utilization management tools, like prior authorization and other "procedures used by the organization to control utilization of services and expenditures." Other commenters expressed concern that limiting prior authorization will lead to redundant, unnecessary, and inappropriate care.

Response: In the proposed rule, we acknowledged that utilization management tools, including prior authorization, are expressly referenced at section 1852(c)(1)(G) and (c)(2)(B) of the Act, as part of the disclosure obligations of MA organizations. We also stated that section 1852(g)(1)(A) of the Act states that MA organizations shall have a procedure for making determinations regarding whether an enrollee is entitled to receive a health care service and that such determinations must be made on a timely basis; that provision applies to both prior authorization determinations and to post-service decisions about coverage and payment. We proposed at § 422.138(a) that coordinated care plans may use prior authorization processes for basic benefits and supplemental benefits, to ensure basic benefits are medically necessary based on standards specified in § 422.101(c)(1), or to ensure that the furnishing of supplemental

benefits is clinically appropriate. Thus, under our proposal and as finalized here, coordinated care plans are still permitted to use prior authorization as a utilization management tool. However, the use of prior authorization is subject to a number of new limitations, which we proposed to ensure that MA enrollees receive the Part A and Part B benefits to which they are entitled.

We proposed, and are finalizing, at § 422.138(b)(1) through (3) that coordinated care plans may use prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure basic benefits are medically necessary based on standards specified in § 422.101(c)(1), or to ensure that the furnishing of supplemental benefits is clinically appropriate. With regards to supplemental benefits at § 422.138(b)(3), we state that MA organizations may use prior authorization to ensure that the furnishing of supplemental benefits is clinically appropriate. The regulation text uses the term "clinically appropriate" as opposed to "medically necessary" because while supplemental benefits must be medically necessary based on long standing guidance, certain supplemental benefits (that is, SSBCI) may be non-primarily health related. Thus, a standard based on medical necessity may not always be appropriate and using the term "clinically appropriate" is more inclusive of SSBCI that may or may not be primarily health related. As discussed in section III.E.2 of this rule, MA plans are still permitted to use additional coverage criteria when Traditional Medicare coverage criteria are not fully established to determine medical necessity as specified at § 422.101(b)(6). This codifies CMS's existing expectations about the appropriate use of prior authorization and will provide important beneficiary protections that prior authorization processes are not used as a barrier to accessing medically necessary services.

Comment: Several commenters thanked CMS for acknowledging prior authorization as an acceptable and useful utilization management tool. Some commenters stated that prior authorization is necessary to manage care and prevent overutilization. Many of these

commenters supported CMS codifying that prior authorization policies and procedures for coordinated care plans may only be used to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, and for basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1). Other commenters suggested that CMS do more to limit the use of prior authorization, in general. For example, some commenters suggested CMS prohibit prior authorization for certain covered services. One commenter suggested CMS require MA plans to exempt providers participating in value-based models from prior authorization requirements. Another commenter requested that CMS require plans to post prior authorization criteria. Others suggested CMS implement greater oversight over prior authorization policies by requiring plans to submit their policies for CMS to review.

Response: We thank commenters for their comments and suggestions. As previously stated, CMS believes that prior authorization is an acceptable utilization management tool and authorized under the Medicare Advantage statutory provisions at section 1852(c) and (g)(1)(A) of the Act. However, we also believe that appropriate limitations on the use of these policies is necessary, so we are relying on our authority under section 1856(b) and 1857(e)(1) of the Act to adopt regulatory limitations designed to protect beneficiaries and ensure their access to medically necessary (or clinically appropriate in the case of certain supplemental benefits) covered benefits. Section 1852(a) of the Act requires MA plans to cover basic benefits and authorizes coverage of supplemental benefits. Ensuring access to covered benefits is one of CMS's policy goals for the MA program and regulating use of prior authorization to ensure that inappropriate barriers to services are not being established supports that policy goal.

As to suggestions that CMS do more to prohibit the use of prior authorization, we do not believe that we have authority for a sweeping prohibition on *all* use of prior authorization. As to prior authorization requirements for specific services, we did not propose such broad limitations and believe that appropriate investigation and study of such a policy is warranted before it could

be adopted. Our proposals at § 422.138, which we are finalizing, address when and how MA plans may use prior authorization generally, except where prohibited by other rules (for example § 422.113). As previously discussed, the proposals at § 422.138(b)(1) through (3) were made to limit the use of prior authorization processes only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure basic benefits are medically necessary based on standards specified in § 422.101(c)(1), or to ensure that the furnishing of supplemental benefits is clinically appropriate. We are also finalizing, at § 422.112(b)(8), that minimum continuity and coordination of care requirements for coordinated care plans include that 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, and that prior authorization be prohibited for 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.

In response to the suggestion that CMS require MA plans to exempt providers participating in value-based models from prior authorization requirements, we note that MA plans determine through negotiations with providers, the terms by which contracted health care providers are paid, and section 1854(a)(6)(B)(iii) of the Act and CMS regulations at §422.256(a)(2)(ii) prohibit CMS from requiring an organization to contract with a particular health care provider or to use a particular price structure for payment under such a contract. MA organizations have the flexibility to, but are not required to, incorporate value-based payment into their payment arrangements with providers, including the terms on which payments are made (for example, whether payment is available if prior authorization procedures have not been met). We consider participation in such payment arrangements to be a contractual matter between organizations and their contracted providers. Given these limitations, we do not believe CMS has the authority to adopt requirements for these contractual arrangements related to payment between MA organizations and contracted providers.

As to the comment requesting that CMS require MA plans to make prior authorization criteria publicly available, we do not believe adopting that requirement in this rule is necessary. Currently, § 422.111(b)(7) requires MA plans to disclose to enrollees any prior authorization rules and other review requirements that must be met in order to ensure payment for the services. In addition, § 422.202(b)(2) requires MA plans that use a network of providers to communicate practice guidelines and utilization management guidelines to providers and, as appropriate, to enrollees. Finally, the proposed rule "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program" ("Interoperability proposed rule"), which appeared in the Federal Register on December 13, 2022, includes proposals to revise the timelines on which MA organizations make prior authorization decisions, to require use of an application programming interface to identify the covered items and services for which prior authorization is required and related documentation requirements, and for MA organizations to report certain metrics regarding use of prior authorization.[106] Given that proposed rule is pending and the scope of current requirements for MA organizations, we will continue to monitor this area to determine if additional requirements are necessary.

Comment: Some commenters made recommendations regarding PA policies. Many of these commenters suggested CMS require MA plans to implement a number of PA standardizations including timelines, format, and content. Other commenters stated that CMS should standardize prior authorization requirements across all CMS programs. Some commenters requested that CMS establish standards for prior authorization requests in regards to

[106] The scope of that proposed rule is broader than summarized here.

both format and contents. Comments also suggested CMS establish standards regarding timelines for payers to response to requests. Some commenters requested CMS require MA plans to publicly post prior authorization denial rates. Another commenter requested that CMS clarify whether prior authorization policies or procedures that dictate specific definitions of medical diagnoses is considered more restrictive than Traditional Medicare.

Response: We thank commenters for their suggestions. Existing regulations governing organization determinations, which include pre-service requests and prior authorization requests, address many of the issues raised by these commenters. Under the rules at § 422.572(a)(1) related to an expedited organization determination request for a medical item or service (which could include an item or service subject to prior authorization), the MA organization must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request. For a standard organization determination request for a medical item or service (again, which could include an item or service subject to prior authorization), the rules at §422.568(b)(1) require the MA organization to notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. Under certain limited circumstances, an MA organization may extend these adjudication timeframes. Existing regulations also specify that when an MA organization denies an organization determination request for an item or service, the denial notice must use approved notice language in a readable and understandable form; state the specific reasons for the denial; inform the enrollee of his or her right to a reconsideration; describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and comply with any other notice requirements specified by CMS. See §§ 422.568(e) and

422.2267(e)(14) and (e)(16). We did not propose to change the timing requirements for organization determinations.

In addition to these existing requirements that apply to organization determinations that involve PA, CMS recently released the Interoperability proposed rule, **,** which includes proposals to expand access to health information and streamline certain procedures used for prior authorization. The Interoperability proposed rule includes proposals requiring implementation of a HL7® Fast Healthcare Interoperability Resources® (FHIR®) standard Application Programming Interface (API) for electronic access to certain information about pending and approved prior authorization requests, including the reason for a denial of a prior authorization request. In addition, there are proposals to require MA organizations to send decisions within 72 hours for expedited (that is, urgent) requests and seven calendar days for standard (that is, non-urgent) requests, and publicly report certain prior authorization metrics. We believe the proposals in the Interoperability proposed rule, if finalized, may address these commenters' recommendations. As we continue to monitor the needs of the program, we will consider these comments for future rulemaking. Finally, in response to whether prior authorization policies or procedures that dictate specific definitions of medical diagnoses is considered more restrictive than Traditional Medicare, we consider coverage policies that dictate specific definitions of medical diagnoses to be additional coverage criteria that are only authorized in accordance with § 422.101(b)(6) as finalized in this rule. We do not consider internal coverage criteria authorized under § 422.101(b)(6) to be more restrictive than Traditional Medicare when the requirements of that regulation are met. We believe that permitting the use of publicly accessible internal coverage criteria in these limited circumstances and contexts is necessary to promote transparent, and evidence-based clinical decisions by MA plans that are consistent with Traditional Medicare. Additionally, we are finalizing requirements at § 422.137 that require MA plans' UM committees to review all utilization management procedures used by the MA plan. Under these requirements, UM committees are required to ensure compliance with a number of MA rules,

including approving only utilization management policies and procedures that use or impose coverage criteria that comply with the requirements and coverage standards at § 422.101(b) and medical necessity criteria at § 422.101(c)(1).

Comment: Some commenters recommended that CMS clarify how we intend to enforce these new utilization management rules and the prior authorization requirements at new section § 422.138. One commenter suggested CMS establish third party reviews of prior authorization denials. Another commenter suggested that CMS develop a process for providers to report when MA organizations are not following these rules.

Response: We thank commenters. CMS currently monitors MA organization compliance with this existing policy through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations alert CMS to any issues with access to care, and CMS may require MA plans to address these matters if they arise. CMS intends to continue these oversight operations to ensure MA organizations' compliance with the final rule.

Comment: Some commenters requested that CMS revise the proposed good cause language at 422.138(c), stating that the proposed language is too broad and may be interpreted too broadly by plans. Some commenters suggested that CMS should not continue to allow coverage decisions to be reopened under the provisions at § 422.616. Another commenter suggested we revise § 422.138(c) to state that "…unless the MAO has evidence of good cause or fraud or similar fault" to prevent plans from abusing their authority here.

Response: We thank commenters for their comments and suggestions. Under the reopening rules at § 422.616(a), an organization determination made by an MA organization is one of the types of decisions that may be reopened and revised by the MA organization under the rules in 42 CFR part 405, subpart I. The application of the reopening rules at § 405.980(b) permit an MA organization to, among other reasons, reopen an organization determination within 1 year from the date of the initial determination for any reason; in addition, reopenings are

permitted within 4 years for good cause; at any time to where there is reliable evidence that the initial determination was procured by fraud or similar fault; and for other specified reasons. However, under the new provision we proposed at § 422.138(c), if an 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. We proposed that if the MA organization has the authority to reopen on the basis of good cause or fraud or similar fault, it may do so consistent with the rules at § 422.616 which cross-reference the reopening rules at § 405.980. An MA organization may reopen an approved organization determination made through a prior authorization or pre-service determination within 4 years from the date of the organization determination for good cause as defined in § 405.986 or at any time if there exists reliable evidence as defined in § 405.902 that the organization determination was procured by fraud or similar fault as defined in § 405.902. Under new § 422.138(c), an MA organization is not permitted to reopen an organization determination on the basis of a lack of medical necessity for any of the other reasons described in § 405.980(b) (for example, for any reason within 1 year) if the approval was made pursuant to a prior authorization or pre-service organization determination process. In other words, an MA organization cannot subsequently reopen and revise such a decision on a later finding of a lack of medical necessity.

We believe that the commenter's suggested revision with respect to an MA organization having evidence of good cause or fraud or similar fault is redundant of what is already stated in the proposed regulation text and therefore, there is no need to revise the proposed regulation text exactly as suggested. However, for added clarity, we are finalizing the regulation text with modifications to make clear that the types of decisions contemplated in § 422.138(c) cannot be reopened except for good cause (as provided in § 405.986) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. We further clarify in §

422.138(c) that the definitions of the terms “reliable evidence” and “similar fault” in § 405.902 of this chapter apply to this provision.

Comment: Some commenters supported CMS’ decision not to propose an amendment to § 422.136 and to, therefore, continue the current rules permitting step therapy for Part B drugs. Some commenters disagreed with CMS’ clarification that we did not authorize step therapy practices for Part A or Part B (non-drug) items or services as part of adopting the Part B drug step therapy regulation, and requested that CMS allow plans to apply step therapy to covered non-drug items and services. Other commenters expressed disappointment with CMS’ continued allowance of step therapy of Part B drugs and suggested that the continued allowance of step therapy for Part B drugs contradicts our proposal that MA plans not impose clinical criteria that are stricter than original Medicare. Some commenters requested that CMS more explicitly differentiate and explain the rules around step therapy for part B drugs and the step therapy for other non-drug Part A and B services, including DME. One commenter suggested that if CMS keeps step therapy for Part B drugs, we should require step therapy policies to be consistent with clinical guidelines and peer-reviewed supporting evidence, adopt certain Part D oversight policies, and require plans to disclose all step therapy policies to beneficiaries before enrollment. This commenter also requested that CMS prohibit plans from requiring an off-label Part B drug when an on-label drug is available.

Response: We thank commenters for expressing their comments and concerns. To clarify, the utilization management policies discussed in this rule do not limit MA organizations’ ability to use step therapy for Part B drugs when it is permitted under § 422.136. Under this final rule, certain utilization management processes, such as clinical treatment guidelines that require an item or service (that is not a Part B drug) to be furnished prior to receiving the requested item or service, would violate § 422.101(b) and (c), and thus, those utilization management processes are prohibited unless it is specified within the applicable NCD or LCD or Medicare statute or regulation when Traditional Medicare coverage criteria are fully established. When Traditional

Medicare coverage criteria are not fully established under § 422.101(b)(6)(i), this final rule permits utilization management policies as part of an internal coverage policy when the current evidence in widely used treatment guidelines or clinical literature expressly supports the use of such utilization management policies and the MA organization complies with policies at § 422.101(b)(6).

We believe there are a number of differences between step therapy for Part B drugs and guidelines for non-drug items and services that require another item or service be furnished prior to receiving the requested item or service. From a clinical standpoint, there tends to be more than one drug that has demonstrated success in treating a certain disease or condition, and also there are generic alternatives, which is somewhat different than other Part A and B services. Additionally, as discussed in the proposed rule, we believe that § 422.136 can put MA organizations in a stronger position to negotiate lower pharmaceutical prices with drug manufacturers, reducing the cost sharing and potentially other out of pocket costs like premiums or costs for other benefits for MA enrollees. Reducing drug costs for beneficiaries remains a top concern of CMS. Additionally, as stated in the 2019 rule (84 FR 23856), MA plans have been and remain subject to the MA regulations and must comply with national and applicable local coverage determinations. Step therapy protocols for part B drugs cannot be stricter than an NCD or LCD with specified step therapy requirements. We believe that this interpretation of § 422.136 is consistent with this rule.

We acknowledge the concerns about the potential for step therapy programs for Part B drugs to deviate from existing clinical guidelines and peer-reviewed supporting evidence, but believe that § 422.136 adequately addresses this. Per § 422.136(b)(5), the P&T committee used by an MA plan to review and approve its Part B step therapy programs must 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 the P&T committee determines appropriate. Similarly, we believe existing

MA regulations adequately address disclosure of Part B step therapy policies to beneficiaries before enrollment. Per § 422.136(a)(2), MA organizations must have policies and procedures to educate and inform providers and enrollees of any Part B step therapy program used by the MA plan. Per § 422.111(b)(2), MA plans are required to disclose accurate information about benefits coverage, including applicable conditions and limitations on benefits coverage. MA plans that apply step therapy to Part B drugs must disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) (when initially adopted or subsequently changed) and Evidence of Coverage (EOC) documents as part of their obligations under § 422.111 (84 FR 23854). As to the recommendation that CMS prohibit MA plans from requiring an off-label Part B drug when an on-label is available, we did not propose this additional limitation to the existing rule at §422.136(c). Step therapy for Part B drugs regulations at §422.136(c), state that 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. This type of substantive change in the regulation would require additional rulemaking; we may consider this issue as part of future policy development but currently believe that the reasons for adopting § 422.136(c) are sufficient (See 84 FR 23855 and 23863). Finally, in response to this recommendation that we adopt certain Part D oversight methods and apply them to Part B drug step therapy programs, we did not propose any changes to §422.136, thus we cannot finalize any of these recommendations in this rule. However, we will continue to monitor step therapy for Part B drug programs in MA and will consider these recommendations in any future rulemaking on this subject.

Comment: Some commenters expressed concerns about the OIG report. One commenter stated that the study only looked at 250 denials during a short time period and thus was not enough to indicate a complete understanding of the use and impact of prior authorization in Medicare Advantage. This commenter also asserted that a Kaiser Family Foundation (KFF)

study,[107] which used CMS data, presented different findings from the OIG report and thus does not demonstrate a problem with prior authorization in MA. Another commenter stated that the OIG report stated that among payment requests that were denied, 18 percent met Medicare coverage rules and MAO billing rules and that most of the payment denials in their sample were caused by human and system processing errors. This commenter asserted that the findings of the report were based on human error and that as the proposal does not focus on issues related to human error, it will have a limited impact. Another commenter stated that the OIG report highlighted a small percentage of denials and thus CMS proposals based on the report will have a limited impact.

Response: We thank commenters for their comments. The OIG report found that, among the prior authorization requests that MA organizations denied, 13 percent met Traditional Medicare coverage rules and that these services likely would have been approved for these beneficiaries under Traditional Medicare. This is an important finding and we believe that modification of MA coverage rules is appropriate and necessary to ensure MA enrollees have access to Part A and B services as required by the Medicare statute. In response to the comment that the OIG report was too limited to make any broad statements about MA, we note that a Health Affairs study[108] came to similar conclusions and similarly found that 15 percent of denials were tied to additional plan coverage criteria. Thus, we do not believe that the OIG's findings, as detailed in their report, are isolated. With respect to the differences between the KFF and OIG studies, we note that different data and methods were used. The KFF study analyzed data from the CMS 2021 Parts C and D Reporting Requirements Public Use File (PUF).[109] These data represent a contract-level reporting of, among other things, all Part C Organization Determinations and Reconsiderations for the 2021 coverage year. In other words, these data are

[107]https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/
[108]https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01054
[109] https://www.cms.gov/files/zip/2021-parts-c-and-d-reporting-requirements-puf-not-incl-part-d-mtm-data.zip

reported at a high level and only account for the number of appeals for each contract that are at a particular stage in the appeals process.[110] As KFF noted in their presentation regarding the data limitations, "Medicare Advantage insurers are not required to indicate the reason a denial was issued in the reporting to CMS, such as whether the service was not deemed medically necessary, insufficient documentation was provided, or other requirements for coverage (such as trying a more basic service first) were not met."[111] Thus, the CMS Reporting Requirements in the PUF do not account for more granular and detailed data that one would find in the full case record for each determination, including medical records and a medical necessity review conducted by a physician. By contrast, the OIG study did include "reviews by health care coding experts and the clinical reviews by physicians" from the case records studied.[112] Therefore, we believe the OIG study presents appropriate and sufficient evidence regarding the reasons for MA coverage denials and how they differ from coverage policy in Traditional Medicare.

In response to the assertion that the OIG report found that denials were based on human error, we note that the OIG report stated that among the payment requests that MAOs denied, 18 percent met Traditional Medicare coverage rules but that many of the payment denials in their sample were caused by human error during manual claims-processing reviews as well as system processing errors. This statement was made in regards to payment denials, not prior authorization requests. Prior authorization requests and payment requests are not the same as described by OIG in the report.[113] Prior authorization requests are made to receive authorization for certain services before the MAO will provide coverage and payment where payment requests are made to receive reimbursement for services that the providers have already delivered to beneficiaries.[114] The OIG report attributed human errors to payment requests specifically and we do not believe that is a basis to dismiss the totality of the OIG report findings and the concerns

[110] https://www.cms.gov/files/zip/2021-reporting-requirements-puf-tech-specs.zip
[111] https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/
[112] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf
[113] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf
[114] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

raised about whether MA plans are furnishing, arranging for, and paying for Part A and B benefits for their enrollees. Finally, while we believe the OIG findings are significant, even if only a few MA organizations are using more restrictive criteria than used in Traditional Medicare, it is important to codify clearer rules on how coverage of Part A and B benefits must be covered and furnished in the MA program to ensure that utilization management tools are used, and associated coverage decisions are made, in ways that ensure timely and appropriate access to medically necessary care for beneficiaries enrolled in MA plans.

Comment: We received some comments requesting that CMS delay the implementation date of all the UM related provisions in this rule, including the new prior authorization requirements at § 422.138. These commenters requested that CMS delay the implementation date to 2026 to better align with the requirements in the Interoperability rule (87 FR 76238).

Response: We thank commenters for their suggestions. We believe that many coordinated care plans are already using prior authorization to confirm diagnoses or other medical criteria, to determine medical necessity of basic benefits, and to ensure the clinical appropriateness of supplemental benefits as proposed at the new § 422.138(b)(1) through (3). Therefore, we do not believe that these requirements present such burden that they should be delayed. In regards to basic benefits, these requirements state that prior authorization may only be used to confirm diagnosis or other medical criteria that are the basis for coverage determinations for the specific item or service and to ensure that an item or service is medically necessary based on the new standards specified in § 422.101(c)(1). However, we believe providing further clarification to coordinated care plans on how Parts A and B benefits should be covered and furnished, including the appropriate role or prior authorization, is necessary. We believe it is important to implement these rules as soon as possible.

After careful consideration of all comments received, and for the reasons set forth in the final rule and in our responses to the related comments in sections III.E.3 of this final rule, we are adopting the new regulation at § 422.138 substantially as proposed with minor modifications

to clarify the text. Specifically, we are including that prior authorization processes include all policies and procedures used in prior authorization unless otherwise noted.

4. Continuity of Care

In addition to the requirements of section 1852(d) of the Act, § 422.112(b) requires MA organizations that offer coordinated care plans to ensure continuity of care and integration of services through arrangements with contracted providers. Requirements in § 422.112(b)(1) through (b)(7) detail specific arrangements with contracted providers by which MA coordinated care plans are to ensure effective continuity and integration of health care services for their enrollees. This includes requiring MA coordinated care plans to have policies and procedures that provide enrollees with an ongoing source of primary care, programs for coordination of plan services with community and social services, and procedures to ensure that the MA coordinated care plan and its provider network have the information required for effective and continuous patient care and quality review.

a. Stakeholder Feedback

Stakeholders have communicated to CMS that MA coordinated care plans' prior authorization processes sometimes require enrollees to interrupt ongoing treatment. We also have received feedback that MA plans require repetitive prior approvals for needed services for enrollees that have a previously-approved plan of care or are receiving ongoing treatments for a chronic condition. When MA plans require repetitive prior approvals, enrollees may face delays in receiving medically necessary care or experience gaps in care delivery that threaten an enrollee's health.

b. Proposed Regulatory Changes

We believe the inclusion of additional continuity of care requirements at § 422.112 will help ensure coordinated care plans comply with and implement the statutory requirement (in section 1852 of the Act) that MA plans provide access to all medically necessary Traditional Medicare (that is, Part A and Part B) benefits that MA plans must cover. We proposed to add a

new paragraph (b)(8)(i) and (ii) at § 422.112 to establish two new requirements for the use of prior authorization by MA coordinated care plans for covered Part A and B services (that is, basic benefits as defined in § 422.100(c)). Section 422.112(b) requires MA organizations offering coordinated care plans to ensure continuity of care and integration of services through arrangements with contracted providers that include the types of policies, procedures and systems that are specified in current paragraphs (b)(1) through (b)(7). First, we proposed at § 422.112(8)(i) that MA coordinated care plans must have, as part of their arrangements with contracted providers, policies that when enrollees are undergoing an active course of treatment, approved prior authorizations must be valid for the duration of the entire approved course of treatment or service. Under our proposal, if an MA coordinated care plan has approved a prescribed or ordered course of treatment or service for which the duration is 90 days, then the MA coordinated care plan's prior authorization approval must apply to the full 90 days, and the MA coordinated care plan may not subject this treatment or service to additional prior authorization requirements prior to the completion of the approved 90-day treatment or service. We also explained that if the MA coordinated care plan approves a prescribed or ordered course of treatment for a series of five sessions with a physical therapist, the MA coordinated care plan may not subject this active course of treatment or service to additional prior authorization requirements. We solicited comment on whether the prior authorization should be required to be valid for the duration of the prescribed order or ordered course of treatment provided that the criteria in proposed § 422.101(b) and (c) are met. Second, at § 422.112(b)(8)(ii)(A), we proposed to define "course of treatment" as a prescribed order or ordered course of treatment for a specific individual with a specific condition, as outlined and decided upon ahead of time, with the patient and provider and clarified that a course of treatment may, but is not required to be part of a treatment plan. We also proposed to define an "active course of treatment" at § 422.112(b)(8)(ii)(B) as a course of treatment in which a patient is actively seeing a provider

and following the prescribed or ordered course of treatment as outlined by the provider for a particular medical condition.

Additionally, we proposed at § 422.112(b)(8)(i)(B) that MA organizations offering coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization that provide for a minimum 90-day transition period for any ongoing course(s) of treatment when an enrollee has enrolled in an MA coordinated care plan after starting a course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider. We explained that this includes enrollees who are new to an MA coordinated care plan having either been enrolled in a different MA plan with the same or different parent organization, or an enrollee in Traditional Medicare and joining an MA coordinated care plan, and beneficiaries new to Medicare and enrolling in an MA coordinated care plan.

We explained that under our proposal, during the initial 90 days of an enrollee's enrollment with an MA coordinated care plan, the MA coordinated care plan would not be permitted to subject any active course of treatment (as defined at the proposed § 422.112(b)(8)(ii)(B)) to additional prior authorization requirements, even if the service is furnished by an out-of-network provider. We explained how we expect any active course of treatment to be documented in the enrollee's medical records so that the enrollee, provider, and an MA plan can track an active course of treatment to avoid disputes over the scope of this proposed new requirement. We also explained that we intended that an active course of treatment covered by the proposal could include scheduled procedures regardless of whether there are specific visits or activities leading up to the procedure. We explained that under the proposal, if an enrollee has a procedure or surgery planned for January 31st at the time of enrollment in a new MA coordinated care plan effective January 1st, the new MA coordinated care plan would be required to cover the procedure without subjecting the procedure to prior authorization because it is within the 90-day timeframe. In this example, the planned surgery is a

part of an active course of treatment and thus would not be subjected to prior authorization by the MA coordinated care plan in which the beneficiary has newly enrolled under the proposed new § 422.112(b)(8)(B). In proposing to limit the way MA coordinated care plans use prior authorization for enrollees undergoing an active course of treatment, CMS seeks to ensure the availability and accessibility of basic benefits, which is consistent with section 1852 of the Act. CMS proposed to use a 90-day transition policy here because it mirrors Part D transition requirements and using the same period will ensure consistency across the MA and Part D programs. In addition, use of one consistent transition period will likely make it easier for new enrollees to understand their transition coverage. We solicited public comment on alternative timeframes for transition periods of ongoing treatment, including the clinical and economic justification for alternative proposals.

We outlined in the proposed rule CMS's authority to adopt the proposed new requirements for MA coordinated care plans. In addition, we noted and briefly explained how CMS implemented a similar policy regarding coverage during a transition period using CMS's authority to negotiate bids and with a similar explanation in the 2005 final rule (70 FR 4193); CMS has similar negotiation authority in the MA program. As explained in the December 2022 proposed rule, we believe it is appropriate to incorporate a similar beneficiary protection and coverage requirement in the MA program to address the transition for new enrollees.

Coordinated care plans are already required to ensure continuity of care and integration of services through arrangements with contracted providers at 422.112(b). Therefore, some MA organizations may already be exercising discretion to eliminate or waive prior authorization for enrollees undergoing an active course of treatment. However, prior to our proposed rule, CMS received anecdotal feedback from stakeholders that care transitions can be difficult for enrollees due to MA plan processes that require new coverage decisions when an enrollee transitions from one MA plan to another. We are not aware of the extent to which current MA plans are already ensuring continuity of care in the way our proposals would require, nor do we have a strong basis

upon which to quantify how often this type of transition occurs. Therefore, we solicited stakeholder input on both of these assumptions: that some MA plans are providing continuity of care, as defined in the proposed § 422.112(b)(8) today and the lack of available data by which to quantify it.

In summary, CMS proposed to add new continuity of care requirements to § 422.112(b)(8), to require that approval of a prior authorization be valid for the entire duration of the approved course of treatment, and that plans provide a minimum 90-day transition period when an enrollee who is currently undergoing an active course of treatment switches to a new MA plan. We thank commenters for their input on CMS's proposed new MA continuity of care requirements.

We received the following comments on this proposal, and our response follows:

Comment: A majority of commenters expressed support for the proposal to require that any plan approval of a prior authorization request from a provider on behalf of an enrollee, or from an enrollee directly, for a course of treatment be valid for the entire duration of the approved course of treatment. Supporters cited that MA plans often approve treatments in increments that may not be clinically supported or medically appropriate, which can be disruptive to care. Other commenters requested clarification as to whether a plan is required to approve the exact course of treatment included in the original coverage request, or whether an MA plan may approve a course of treatment that differs from what was ordered or prescribed by the provider. Several commenters requested that CMS give deference to providers when establishing a course of treatment. Several other commenters expressed concern that requiring a prior authorization be valid for an entire duration of the approved course of treatment is overly broad, and could lead to the continuation of treatments that are no longer medically necessary. Several commenters stated that the requirement conflicts with MA plans' obligations to ensure access to medically necessary care, and impedes MA plans' ability to manage care through strategies that ensure quality and control unnecessary cost. Some commenters suggested that

there are situations where a prior authorization and plan of care should be revisited, and the course of treatment be revised, if the patient is not responding as expected. Some commenters suggested that CMS allow limitations on the duration of approvals to ensure there are opportunities to reassess medical necessity at reasonable intervals.

One commenter suggested that CMS modify the proposal to allow limits on the duration of the prior authorization that are consistent with guideline-suggested reassessment of disease, in cases where treatments may be indefinite (for example, in cases of chronic illnesses). Another commenter suggested that the definition of "active course of treatment" should be aligned with industry standards, specifically: (1) a course of treatment for a serious and complex condition, which includes a condition that is serious enough to require specialized medical treatment to avoid the reasonable possibility of death or permanent harm, or a condition that is life threatening, potentially disabling, degenerative, or congenital, and requires specialized medical care over a prolonged period of time; (2) course of institutional or inpatient care; (3) scheduled nonelective surgery, including related postoperative care; (4) a course of treatment for a pregnancy; and (5) treatment for a terminal illness. Several commenters requested clarification as to whether there are a minimum number of days that constitute a "course of treatment." Another commenter requested that CMS explicitly define "course of treatment" in reference to Traditional Medicare coverage and benefits benchmarks (for example, the mean Length of Stay for a given Medicare Severity Diagnosis Related Group). Finally, one commenter requested additional examples of what is and is not permissible to ensure treatments that are not medically necessary under Traditional Medicare guidelines are not required to be covered under this policy.

Response: CMS would like to thank all commenters for providing feedback on the proposed regulation. We understand the concerns that the proposal could result in the continuation of medically unnecessary care, which in turn could result in waste and increased costs. However, as highlighted in the preamble, over the past several years, we have received feedback from many stakeholders, including enrollees and providers, that MA plans often require

repetitive prior approvals for needed services, even when enrollees have a previously-approved course of treatment, plan of care, or are receiving ongoing treatments for a chronic condition. The feedback we have received consistently outlines how this practice delays medically necessary care and can cause gaps in care delivery that threaten an enrollee's health, sometimes leading to negative outcomes. For that reason, we believe this proposal is essential to minimize such delays and disruptions to care for MA enrollees.

We agree that clarification of the policy being finalized will help ensure the new regulation is implemented appropriately. Therefore, we are finalizing the revisions at § 422.112(8)(i)(A) with modifications from the proposed rule, to require that an 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 patient's medical history (for example, diagnoses, conditions, functional status), and the treating provider's recommendation. The determination of medical necessity to establish the duration of the approved course of treatment must be made consistent with § 422.101(c); any adverse determination on medical necessity, such as approval of a duration that this less than the requested duration for the course of treatment, must be reviewed in accordance with § 422.566(d) (and § 422.629(k) for an applicable integrated plan) before an MA plan may issue the determination. Further, the coverage policies governing these determinations must also comply with § 422.101(b). This will ensure that services delivered during the approved and previously authorized course of treatment remain consistent with Medicare coverage guidelines, are reasonable and necessary for the individual enrollee, and do not overly burden the provider with unnecessary and repeated prior authorization requests.

CMS is not requiring a minimum or maximum number of days for a course of treatment, since the necessary scope and duration of a course of treatment can vary widely from enrollee to enrollee and should be based upon the individual's needs and medical necessity. We believe flexibility is necessary to accommodate the varying complexities of a multitude of conditions for

which an enrollee may be receiving care, and recognize that many treatment courses last for varying periods of time and may require varying amounts of interventions that are unique to the individual being treated.

In response to comments expressing concern over the potential for treatment continuing indefinitely or recommending that treatments should be revisited at certain intervals, we believe that in many cases additional evaluation of the patient to ensure ongoing medical necessity and efficacy of treatment at certain intervals will be required or recommended and supported by the relevant coverage criteria, or by the patient's medical needs and the treating provider's recommendation. Under this final rule, all decisions for prior authorization, including those involving the authorization of treatment that lasts over a period of time, must be made in accordance with §422.138. This means that prior authorization may only be used to confirm the presence of a diagnosis or other medical criteria that are the basis for coverage or to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1). In order for an approval of a prior authorization request for a course of treatment to last indefinitely, it would have to be medically necessary and supported by the applicable coverage criteria, and the patient's medical condition and provider's recommendation. Therefore, we believe it would be uncommon that a MA organization would be required to approve a request for a treatment indefinitely. Additionally, where prior authorization is used by fee-for-service Medicare, the use of prior authorization by the MA organization on the same services must apply the fee-for-service Medicare standards based on §422.101(b)(2). Further, pursuant to §422.138(c), 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 unless the MA organization has the authority to reopen the decision for good cause or fraud or similar fault per the reopening provisions at § 422.616.

An MA plan may approve and authorize treatment for a different period of time than the treating provider's ordered course of treatment if the plan has determined that what was ordered or prescribed by the treating provider was not medically necessary or appropriate based on the enrollee's condition or diagnosis. The following example illustrates how this modification will work in practice:

The patient is a type 1 diabetic. The treating provider orders a course of treatment that consists of continuous subcutaneous insulin infusions for a period of 3 months. The treatment is subject to prior authorization. In order to apply prior authorization, the MA plan must follow the requirements of § 422.101(b), and apply any applicable coverage criteria for the service. The applicable NCD[115] for infusion pumps requires that "continued coverage of the insulin pump would require that the patient be seen and evaluated by the treating physician at least every 3 months." Additionally, the patient's medical history does not indicate a need for more frequent evaluations. Here, it would be appropriate, under our proposal, for the MA plan to issue a prior authorization approval of the service for a period of 3 months because the NCD requires that the patient be evaluated at least every 3 months, and the treating provider ordered the course of treatment for 3 months. If the patient's medical history and the treating provider suggests possible complications in treatment, it may be appropriate for the MA plan to authorize approval of the service for a period of less than 3 months.

However, MA plans should not shorten authorization periods that are outlined in Traditional Medicare coverage criteria. The only instances where an MA plan may use a shorter (or different) periodicity or frequency of evaluation or other such review would be if the change were consistent with the relevant coverage criteria, and supported by the evidence in the patient's medical record, and by treatment guidelines or clinical literature that is widely available. This must be clearly documented and referenced by the MA plan in the prior authorization decision. Moreover, in all instances, we expect the MA plan and its contracted provider to coordinate care

[115] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=223&ncdver=2

to ensure that the prior authorization is approved for a period that ensures that care is delivered for as long as is medically necessary and that minimizes disruptions in care for the enrollee. In other words, the MA plan may not establish blanket rules for the duration of an authorization associated with course of treatment decisions for purposes of convenience or simplicity; the duration of a prior authorization must be valid for as long as medically necessary to avoid disruptions in care and not in conflict with applicable coverage criteria.

Comment: A few commenters stated that care should not be based solely on a physician's order, but include other provider types when appropriate.

Response: As outlined in the preamble and proposed regulatory text, a course of treatment is a prescribed or ordered course of treatment for a specific individual with a specific condition that is outlined and decided upon ahead of time with the patient and the treating provider. The term "provider" is defined in § 422.2 to mean an individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State and an entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation. This definition is not limited to physicians. Therefore, the definition of course of treatment we proposed and are finalizing at § 422.112(b)(8)(ii)(A) includes courses of treatment ordered by non-physician health care providers.

Comment: Several commenters requested clarification regarding whether and how the continuity of care provisions apply specifically to Part B drugs, and how the "entire prescribed or ordered course of treatment" would be determined where a drug may be used indefinitely. One commenter requested clarification that the continuity of care proposal include all new enrollees who are actively receiving physician-administered drugs that are covered under Medicare Part B, not just existing enrollees.

Response: As discussed in the preamble, these provisions apply two new requirements for the use of prior authorization by MA coordinated care plans for covered Part A and B

services (that is, basic benefits as defined in § 422.100(c)). This includes relevant Part B drugs. In order to provide additional guidance and clarity, we are finalizing § 422.112(b)(8)(i) with changes from the proposal to ensure that enrollees do not have disruptions in care due to additional prior authorization requirements; these changes from the proposal are in response to comments. We are finalizing § 422.112(b)(8)(i)(A) to require that an approval of a prior authorization request for a course of treatment be valid for as long as medically necessary to avoid disruptions in care, in accordance with applicable coverage criteria, the patient's medical history, and the treating provider's recommendation. In cases where a drug being used indefinitely is medically necessary and consistent with the relevant coverage criteria, the patient's medical history and the provider's recommendation, we encourage MA coordinated care plans to work with the provider to assess continued efficacy and medical necessity as is reasonable; this type of coordination is consistent with how § 422.112(b) requires MA organizations offering these plans to have arrangements (which meet the minimum requirements in paraphs (b)(1) through (b)(8)) to ensure continuity of care and integration of services.

In response to the comments, we clarify that the transition period required by § 422.112(b)(8)(i)(B), as proposed and finalized, applies, beginning with coverage January 1, 2024, to all new enrollees who are undergoing an active course of treatment— including where the active course of treatment is taking a physician-administered drug covered under Part B. An 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.

Comment: Several commenters requested that CMS clarify whether a course of treatment includes inpatient services, skilled nursing facilities (SNF), home health care (HHC), and other post-acute care. One commenter suggested that the regulatory text be amended at 422.112(b)(8)(ii)(B) so that continuity of care applies where "an active course of treatment includes transfer of a patient to another inpatient provider."

Response: We clarify here that an active course of treatment may include situations when a patient is transferred from an acute inpatient setting to a SNF, HHC, and care in other post-acute care settings. However, this new regulation does not change or affect how section 1853(g) of the Act and § 422.318 assign financial responsibility for inpatient services from one of the facilities listed in § 422.318(a) (a "subsection (d) hospital" as defined in section 1886(d)(1)(B) of the Act, a psychiatric hospital described in section 1886(d)(1)(B)(i) of the Act, a rehabilitation hospital described in section 1886(d)(1)(B)(ii) of the Act, a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B) of the Act, or a long-term care hospital (described in section 1886(d)(1)(B)(iv)) that begin before, and carry over to, the effective date of enrollment in a new MA plan. Under section 1853(g) and § 422.318, when MA plan coverage begins during an inpatient stay, the previous MA plan or Traditional Medicare if the enrollee is joining an MA plan from Traditional Medicare is responsible for payment. CMS reminds commenters that all other relevant Traditional Medicare regulations must also be followed, including those regarding inpatient admissions and terminations.

Comment: One commenter requested that, in addition to ensuring that prior authorizations remain active for a patient's entire course of treatment, CMS adopt language to ensure that surgical or other procedures/services performed incident to a procedure that has received prior approval may not be denied for failure to obtain prior approval.

Response: We thank the commenter for the suggestion, but decline to explicitly prohibit an MA plans from denying coverage of a service provided incident to a course of treatment but not expressly included in the approved course of treatment, because of a failure to obtain prior approval. In the case where a service is provided incident to a procedure, it may be appropriate for the MA plan to conduct a concurrent or retrospective review to determine medical necessity of the incidental procedure. Our proposal was about prior authorization, and we are not adding requirements or limitations on concurrent or retrospective reviews in the final rule.

Comment: A majority of commenters expressed support for requiring a 90-day transition period when an enrollee is new to an MA plan. Other commenters expressed concern that this transition period restricts plans' ability to conduct concurrent reviews, which are necessary for quality control and to prevent waste, fraud, and abuse. Some commenters were concerned that the proposal could potentially require an MA plan to be held responsible for the long-term cost of care provided by an out-of-network provider, or for a treatment that may not meet the standards of their internal coverage criteria, where such criteria are consistent with CMS policies, but utilization management policies may vary. A few commenters stated that the goal of this proposal is already achieved through existing plan specific practices where prior authorization approvals are continued, allowing a provider to demonstrate to the new MA plan that the prior approval already took place and was granted by the previous plan. Several commenters suggested that the transition requirement will put patients at risk of receiving care that is no longer medically necessary. Other commenters expressed concern that requiring a blanket transition period on all services creates a significant burden to MA plans from a technical and procedural perspective, as well as from a claims adjudication perspective. Other commenters requested additional guidance regarding how CMS expects MA plans to implement this requirement. One commenter requested clarification on whether the continuity of care provisions proposed in this rule are satisfied by a plan approving continuation of services or treatment for 90 days to ensure continuity of care if a new member is receiving care from a non-contracted provider when their enrollment in the plan becomes effective, while working with the enrollee to find in-network providers as needed. Finally, a few commenters expressed concern that the transition period may be used as a tactic to delay care by either the plan or by providers aiming to receive a different reimbursement rate—that is, postpone care until the new plan takes over and is, therefore, responsible for paying for services.

Response: As outlined in the preamble and proposed regulatory text, the 90-day transition period only applies to *active* courses of treatment when an enrollee has enrolled in the MA plan

after starting a course of treatment. See also our discussion in the proposed rule at 87 FR 79504 through 79505 about active courses of treatment. As proposed and finalized at § 422.112(b)(8)(ii)(B), an active course of treatment is one in which a patient is actively seeing the provider and following the course of treatment. This does not mean that the active course of treatment must last for the full 90-days, rather this means that the new plan may not subject an active course of treatment to an additional prior authorization for a period of 90 days, beginning the day enrollment in the new plan becomes effective. Because this new requirement is tied to an active course of treatment that began before enrollment in the new MA plan, the transition period applies for the shorter of the 90-day period (though MA plans have the discretion to extend this period) or the end of the active course of treatment.

For example, if an enrollee is undergoing an active course of treatment that is 60 days in duration, and the enrollee transfers to a new MA plan 30 days into that course of treatment, then the MA plan may not subject that course of treatment to a prior authorization requirement for the next 30 days. After that time, the course of treatment is complete and any future treatments may be subject to prior authorization as appropriate. This does not mean that an MA plan may not apply prior authorization to *any* services in the first 90-days of enrollment, but only that active courses of treatment may not be subjected to prior authorization within a 90-day timeframe. We expect that MA plans would use this period to coordinate with the treating provider, or find (or help the enrollee find) a new provider as needed, to satisfy any utilization management policies that may apply at the completion of the 90 days to ensure that there is not a disruption in treatment for the patient. Further, § 422.112(b)(8)(i)(B), as proposed and finalized, does not prohibit concurrent or retrospective review of an active course of treatment. A plan may conduct concurrent reviews as necessary, as long the review does not interfere with an active course of treatment. The MA plan cannot deny coverage of such active courses of treatment on the basis that the active course of treatment did not receive prior authorization (or was furnished by an

out-of-network provider) but may review the services furnished during that active course of treatment against permissible coverage criteria when determining payment.

In response to the comments that the proposal is redundant due to many MA plans already utilizing internal practices for continuing prior authorization approvals, or allowing for a continuation of services, CMS continues to believe that codification and standardization are necessary. While some plans may have internal processes in place to allow for a continuation of services, we are not aware that these practices have been universally adopted and consistently applied by all plans. If plans are already allowing for these types of transitions, then existing practices may already comply with what is proposed.

Finally, since the provision only applies to active courses of treatment, CMS does not foresee the possibility that medically necessary services could or would be delayed solely for the purpose of requiring another plan to pay for that service. If treatment is medically necessary at the time it is ordered, it would be highly inappropriate for that treatment to be delayed solely for the purposes of shifting payment responsibility. While, as stated in the preamble, we have interpreted active course of treatment to include scheduled procedures, regardless of whether there are specific visits or activities leading up to the procedure, it would seem unrealistic for a plan or a provider to know in advance that an enrollee is anticipating leaving an MA organization to join another plan, anticipate the enrollee's departure, and decide to delay a course of treatment so as to pass those costs onto the new plan. Such an action would be a violation of our rules to provide all necessary and appropriate care to enrollees. Further, the new rule requires that the course of treatment must be *active* at the time the patient's enrollment in the new MA plans becomes effective, so the 90-day transition period would not be implicated if care had not begun at the time of enrollment.

Comment: Several commenters requested clarification as to whether after 90 days a plan may apply out-of-network limits, conduct a new review, and issue a new decision. Some commenters stated that plans should be required to extend coverage, on a case-by-case basis, for

patients receiving care after the 90-day period expires and should not impose additional prior authorization requirements (for example. in cases of life sustaining care). Several commenters requested that CMS require plans to notify new enrollees about the transition period, and any changes in benefits.

Response: As outlined in the preamble and the proposed regulation, the minimum 90-day transition period prohibits an MA plan from disrupting or requiring reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days. The transition period is intended to provide enrollees with an assurance of continued care when changing plans, and to minimize disruptions when moving to a new plan that may have differing benefits. After the transition period, a plan may reassess medical necessity and apply out-of-network limits in accordance with plan benefits and other relevant requirements as appropriate. We clarify that § 422.112(b)(8)(i)(B) does not mandate that the new MA plan cover the active course of treatment regardless of other applicable coverage rules (for example, § 422.101(b) or plan coverage policies for supplemental benefits). The MA plan cannot deny coverage of such active courses of treatment on the basis that the active course of treatment did not receive prior authorization or was furnished by an out-of-network provider, but may apply permissible coverage criteria.

At this time, CMS is not adding a requirement for notification to enrollees because pursuant to §422.111(b)(7), MA organizations are required to disclose information to enrollees regarding prior authorization and review rules. This includes the continuity of care provisions outlined in this proposal. CMS urges plans and their contracted providers to work with these transitioning enrollees and their previous treating providers, even if those previous treating providers are not contracted with the receiving plan, during the transition period to ensure that care is continued in the least disruptive manner possible. CMS also notes that the 90-day transition period is a minimum requirement. Therefore, if an active course of treatment is approved by the previous treating provider or plan to last longer than the 90-day minimum, an

MA plan that is newly covering the enrollee may elect to permit the enrollee to finish the course of treatment, which lasts beyond 90 days, before imposing additional prior authorization(s). CMS will consider adding an additional notice requirement during future policymaking.

Comment: One commenter requested CMS require plans to notify enrollees that they should check whether an enrollee's ongoing prescriptions would be covered with the same level of cost-sharing after the initial 90 days of enrollment and, if so, whether any utilization management protocols will apply to these medications.

Response: As outlined in the previous comment response, CMS is not requiring any additional notification requirements at this time. If an on-going Part B prescription is an active course of treatment under the definition at § 422.112(b)(8), then the MA plan may not subject the treatment to additional prior authorization for the first 90 days of enrollment. After the 90-days, prior authorization may be applied in accordance with the prior authorization provisions in this rule. Cost-sharing levels will be based on the specific plan, and are not within the scope of this rule.

Comment: One commenter requested that the 90-day transition period apply when an enrollee who is currently undergoing treatment switches to a new MA plan, switches from a traditional Medicare plan to an MA plan, or is new to Medicare. Another commenter requested clarification on whether MA plans must provide the proposed transition period for any ongoing course of treatment that had been covered under a traditional Medicare coverage policy, regardless of whether there was a prior authorization requirement for that course of treatment in traditional Medicare.

Response: As stated in the regulatory text at § 422.112(b)(8)(i)(B), the transition requirement applies to "…enrollees new to a plan and enrollees new to Medicare..." who are currently undergoing an active course of treatment. This means the requirement applies for any active course of treatment when an enrollee switches to a new MA plan, switches from a traditional Medicare plan to an MA plan, or is new to Medicare. Further, the plan must provide

the transition period, wherein an active course of treatment may not be subjected to prior authorization, for all new enrollees who are undergoing an active course of treatment, regardless of whether the treatment was subject to a prior authorization by a previous plan. As a reminder, "course of treatment" and "active course of treatment" are defined at § 422.112(b)(8)(ii).

Comment: CMS solicited public comment on alternative timeframes for transition periods of ongoing treatment, including the clinical and economic justification for alternative proposals. Several commenters stated that a 30-day policy would provide a more reasonable timeframe to review a previously approved and ongoing plan of treatment, but longer periods could be permitted if medically necessary. One commenter requested that CMS modify the proposal at § 422.112(b)(8)(i)(B) to require MA plans to provide continued coverage for an active course of treatment authorized by the member's prior plan for the remainder of the authorized period or units of service. At least one plan provided feedback that they already have 90-day continuation of care policy in place, and other plans indicated they have similar policies for continuing approvals for ongoing treatments. A few commenters commented that the Part D transition period and the proposed transition period are not analogous. Commenters stated that the costs of Part D drugs are often lower than the costs for medical services, and that differing clinical opinions can lead to differing courses of treatment based on the resources available to the MA plan. Some commenters stated that a 90-day timeframe would be both financially and administratively burdensome to MA plans.

Response: While some commenters indicated that a 90-day timeframe could be financially and administratively burdensome to some MA plans, CMS did not receive specific details to demonstrate that the burden to MA plans outweighs the value of ensuring continuity of care for enrollees. Further, we believe that 90 days is an appropriate amount of time to minimize disruptions in treatment, and to allow plans and providers to ensure continuity and coordination of care. As outlined in the proposed rule, we believe a 90-day transition policy is beneficial because it mirrors Part D transition requirements and using the same period will ensure

consistency across the MA and Part D programs. We understand that there are differences in the costs associated with Part D drugs and with certain medical procedures, however the Part D transition period mandates coverage, whereas § 422.112(b)(8), as previously explained, only prohibits the application of prior authorization requirements for the pre-existing active course of treatment.

Regarding the comments that different plans may offer differing courses of treatment, we do not find this a compelling reason to alter the transition time frame. Since this requirement only affects active courses of treatment, altering the course of treatment when the enrollee enrolls in a new MA plans is precisely the type of disruption this requirement aims to eliminate.

Comment: One commenter requested that CMS clarify that the 90-day transition period applies only to basic benefits and not to supplemental benefits.

Response: As proposed and finalized, the new rules at § 422.112(b)(8)(i) apply to basic benefits only. Per this new regulation, MA coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization for basic benefits that include the new restrictions on use of prior authorization for a course of treatment and an active course of treatment for a new enrollee. An MA organization may elect to extend this policy to supplemental benefits. We note that MA PFFS plans may not use prior authorization processes at all and that MA PPO plans may not use prior authorization processes for out of network services.

Comment: One commenter requested that plans be permitted to conduct their own prior authorization or utilization management review for treatments extending beyond the 90-day transition period. The commenter stated that plans should also be permitted to support an enrollee's transition to an in-network provider at the end of the transition period.

Response: The 90-day period prohibits prior authorization on active courses of treatment, including when the service is furnished by an out-of-network provider. Once the 90 days has elapsed, the plan is permitted to impose prior authorization requirements on the service. After

the 90-day transition period is complete (or the course of treatment has concluded, whichever comes first), the new plan may direct care through in-network providers and apply prior authorization.

Comment: CMS solicited stakeholder input as to whether some MA plans are already providing continuity of care consistent with what CMS proposed at § 422.112(b)(8), as well as any additional information that may be useful for CMS to quantify the burden associated with this proposal. Several stakeholders indicated that some MA plans provide some similar level of continuity care today. Commenters did not provide additional information regarding quantifying the burden associated with implementing the proposal.

Response: CMS thanks the commenters for their feedback.

Comment: Several commenters requested additional time to implement the requirements related to continuity of care, citing that operationalizing these new requirements will involve significant information technology and administrative resources. Commenters requested that the implementation date be moved to 2025 at the earliest. Other commenters suggested an effective date of 2026 would align with CMS' proposed 2026 effective date for its Advancing Interoperability and Improving Prior Authorization proposed rule that also impacts MA plans.

Response: CMS appreciates the intricacies involved with implementing new regulatory requirements. However, since several MA plans indicated they already have existing policies in place that are similar to what CMS proposed at § 422.112(b)(8), and we continue to receive feedback from stakeholders that medically necessary care is being disrupted by unnecessary prior authorization, we believe that it is important to implement this requirement as soon as possible. The new requirements at § 422.112(b)(8) are applicable beginning on and after January 1, 2024, for MA coordinated care plans.

After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments, we are finalizing § 422.112(b)(8) largely as proposed but with modifications. We are finalizing § 422.112(b)(8)(i)(A) with

revisions to require approval of a prior authorization request for a course of treatment be valid for as long as medically necessary to avoid disruptions in care, in accordance with the applicable coverage criteria, the individual patient's medical history, and the treating provider's recommendation.

5. Mandate Annual Review of Utilization Management (UM) Policies by UM Committee (§ 422.137)

We proposed procedural improvements to ensure that utilization management policies are reviewed on a timely basis and have the benefit of provider input. Any authority for MA organizations to use utilization management policies with regard to basic benefits is subject to the mandate in section 1852(a)(1) of the Act that MA plans cover Medicare Part A and Part B benefits (subject to specific, limited statutory exclusions) and, thus, to CMS's authority under section 1856(b) of the Act to adopt standards to carry out the MA provisions. In light of the feedback we received and our concern that enrollees may be facing unreasonable barriers to needed care, we proposed to require MA organizations to establish a Utilization Management (UM) committee to operate similar to a Pharmacy and Therapeutics, or P&T, committee. We proposed to add requirements pertaining to this UM committee in a new regulation at § 422.137.

a. Review and Approval of UM Policies

At § 422.137(a), we proposed that an MA organization that uses UM policies, such as prior authorization, must establish an UM committee that is led by an MA plan's medical director (described in § 422.562(a)(4)). Section 422.562(a)(4) requires every MA organization to employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity and establishes that the medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. We also proposed, at § 422.137(b), that an MA plan may not use any UM policies 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. This proposal would ensure that plan policies and procedures meet the standards set forth in this final rule beginning with the contract year after the finalization of this proposed rule. We explained that we anticipate that there will be sufficient time between our issuance of a final rule and January 1, 2024, for each MA organization to engage in the necessary administrative activity to establish the UM committee and have its existing UM policies reviewed and, if they meet the standards in this proposed regulation, approved for use.

We proposed the committee responsibilities at § 422.137(d). The responsibilities would include that the UM committee, at least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. We proposed at § 422.137(d)(1)(i) through (iii) that such review must consider--

- The services to which the utilization management applies;
- Coverage decisions and guidelines for original Medicare, including NCDs, LCDs, and laws; and
- Relevant current clinical guidelines.

We proposed at § 422.137(d)(2)(i) though (iv) the committee approve only utilization management policies and procedures that:

- Use or impose coverage criteria that comply with the requirements and standards at § 422.101(b);
- Comply with requirements and standards at § 422.138(a)–(c);
- Comply with requirements and standards at § 422.202(b)(1); and
- Apply and rely on medical necessity criteria that comply with § 422.101(c)(1).

Currently, § 422.202(b) requires MA organizations to establish a formal mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures; that formal mechanism for consultation must ensure that

certain standards are met. Specifically, § 422.202(b)(1)(i) through (iv) require that MA plan practice guidelines and UM guidelines must: (i) be based on reasonable medical evidence or a consensus of health care professionals in the particular field; (ii) consider the needs of the enrolled population; (iii) be developed in consultation with contracting physicians; and (iv) be reviewed and updated periodically. We proposed to modify § 422.202(b)(1)(i) to align it with our standard for creating internal coverage criteria. We therefore proposed to replace the requirement that practice and UM guidelines be based on reasonable medical evidence or a consensus of health care professionals in the particular field with a requirement that UM guidelines be based on current widely used treatment guidelines or clinical literature. This is consistent with the proposed coverage criteria requirements at § 422.101(b)(6), which are discussed in detail in section III.E.2. of this final rule.

We solicited comment on whether we should also require the UM committee to ensure that the UM policies and procedures are developed in consultation with contracted providers; whether the UM committee should ensure that the MA organization, as required by § 422.202(b)(2), communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees; and whether the UM committee should have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies. We also proposed at § 422.137(d)(3) that the committee must revise UM policies and procedures as necessary, and at least annually, to comply with the standards in the regulation, including removing requirements for UM for services and items that no longer warrant UM so that UM policies and procedures remain in compliance with current clinical guidelines. We explained that mandating annual review of utilization management policies using these standards will help ensure that medically necessary services are accessible to all enrollees. Because prior authorization and referral or gatekeeper policies are included in UM policies and procedures,

these proposed requirements would apply as well to those polices and CMS expects MA organizations to update their UM policies after the UM committee approves or revises them.

As this final rule as a whole makes clear, ensuring that enrollees have access to and are furnished covered benefits is a priority. We solicited comment on whether to require the UM Committee to review all internal coverage criteria used by the MA plan. We also solicited comment on the extent to which the proposed regulation text sufficiently and clearly establishes the standards and requirements discussed here.

b. Utilization Management Committee Membership

At § 422.137(c)(1) through (4), we proposed that the UM committee must include a majority of members who are practicing physicians; include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan; include at least one practicing physician who is an expert regarding care of elderly or disabled individuals; and 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. These composition requirements are in addition to the proposal that the medical director, required for each MA plan under § 422.562(a)(4), lead the UM committee.

We solicited comment on recommendations for other types of providers, practitioners, or other health care professionals that should also be included on the UM committee and whether additional standards for composition of the UM committee are necessary with regard to expertise, freedom from conflicts of interest, or representation by an enrollee representative. We also solicited comment on whether we should include a requirement, that when the proposed UM committee reviews UM policies applicable to an item or service, that the review must be conducted with the participation of at least one UM committee member who has expertise in the use of, or medical need for that specific item or service.

c. Documentation of Determination Process

We proposed at § 422.137(d)(4) that the UM committee must 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. Finally, we proposed at § 422.137(d)(5) that the UM committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request. We explained that the documentation should provide CMS with an understanding of the UM committee's rationale for their decision, and may include, but is not limited to, information such as meeting minutes outlining issues discussed and any relevant supporting documentation.

d. Interchangeable Use of the P&T and Utilization Management Committees

As discussed in our proposal, we believe it is appropriate that the establishment of an MA plan UM committee, with certain exceptions, largely mirror the requirements in § 422.136 that MA organizations have a pharmacy and therapeutic committee that reviews and approves step therapy programs for Part B drugs and the requirements regarding membership, scope, and responsibilities of that P&T committee. We believe that similar requirements, which were modeled after the longstanding Part D P&T committee requirements at § 423.120(b), are generally adequate for the purposes of the UM committee. We explained that this proposal was designed to require review and approval of utilization management policies, including utilization management policies that use or impose coverage criteria, to ensure that these policies and procedures are medically appropriate, consistent with Medicare coverage rules, and do not negatively impact access to medically necessary services.

To meet the existing requirements at § 422.136(b), MA-PDs are permitted to utilize an existing P&T committee established for purposes of administration of the Part D benefit under part 423 of this chapter. In the proposed rule, we stated that we anticipate that some of the

requirements proposed for the UM committee may overlap or duplicate existing P&T committee requirements in connection with coverage of and utilization management policies for Part B drugs. We solicited comment on whether an MA plan should be permitted to utilize the proposed UM committee at § 422.137 to also meet the existing P&T committee requirements of § 422.136(b), provided that elements and requirements of all applicable regulations governing the committees and their functions (that is, §§ 422.136, proposed 422.137, and 423.120) are met. To the extent that LCD policies and localized or regional professional standards of practice are used by the proposed UM committee in performing its duties, it may not be advisable to permit use of one UM committee to serve multiple functions for diverse service areas. We also solicited comment on whether to explicitly permit an MA organization, or the parent organization of one or more MA organizations, to use one UM committee to serve multiple MA plans, including whether that should be limited to MA plans that are offered under the same contract.

In summary, CMS proposed to require at § 422.137 that all MA organizations that use utilization management policies, such as prior authorization, must establish an UM committee that is led by an MA plan's medical director. Further, we proposed than an MA plan may not use any UM policies 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. We thank all commenters for their input on CMS's proposed new requirements. We received the following comments on this proposal, and our response follows:

Comment: CMS solicited comment on whether MA organizations should be permitted to use one committee to serve multiple plans. Many commenters expressed support for making this allowance. Some commenters recommended that plans maintain the flexibility to define the structure and appropriate additional responsibilities of the UM committee. One commenter requested clarification as to the number of UM committees required, and whether committees are required per plan or per MA organization. One commenter stated that if an MA organization is permitted to use one committee for multiple MA plans, then the final rule should contain specific

requirements related to UM committee membership composition and input from external stakeholders.

Response: CMS appreciates the comments and input regarding this issue. We will allow MA organizations the discretion regarding whether the UM committee is best served at the organization or plan level, and we will not prescribe whether UM committees must be formed at the plan or organization level. This flexibility does not, however, extend to the parent organization of the MA organization (that is, an UM committee cannot serve multiple MAOs). Regardless of whether the MA organization decides to organize its UM committee at the plan or organization level, the MA organization must ensure that the committee's review functions cover the needs of all plans under its organization. If at any time it appears that MA organizations are not fulfilling regulatory requirements regarding the UM committee, then we may engage in further rulemaking regarding whether the UM committee must operate at the organization or the plan level.

As proposed, § 422.137(a) requires the UM committee to be led by a plan's medical director. In light of our decision to interpret and implement § 422.137 by permitting one UM committee to serve multiple MA plans offered by the same MA organization, one plan's medical director may fulfill this role for the MA organization.

Comment: A majority of comments were supportive of requiring MA organizations to establish UM committees. Several commenters pointed out that some accrediting bodies require MA plans to maintain active committees that serve a similar function to the proposed UM committee, and that many plans are already accredited and therefore already have such standing committees. For that reason, some commenters suggested that CMS permit plans to adopt existing committees to fulfil the regulatory requirements of the UM committee. Some commenters also requested that CMS require MA plans to be accredited. One commenter questioned if it would it be permissible to incorporate an UM committee with a credential committee, since both are provider specific and include applicable attendees. CMS also solicited

comment on whether plans should be permitted to use existing P&T Committee to serve as the UM committee. Commenters were generally supportive, but requested that MA plans retain discretion when deciding whether and how to adapt committees to serve multiple functions.

Response: CMS thanks all commenters for providing input regarding the proposed regulations. We appreciate that many plans already have existing committees that are similar in composition and function to the proposed UM committee, including committees required by various accrediting bodies. While we do not believe requiring MA plans to be accredited is necessary or within the scope of this rule, we do believe it is appropriate to permit MA organizations to leverage existing committees to satisfy the new regulatory requirement. Therefore, MA organizations may adapt or alter existing committees, including committees required by accrediting bodies and existing P&T committees, to conform with the regulatory requirements of § 422.137. We emphasize, however, that this flexibility does not change or lessen the composition requirements or duties of the UM committee; all of the requirements in § 422.137 finalized in this rule must be met for the UM committee and if the MA organization is also using that committee to satisfy the requirements of §§ 422.136 and 423.120 for a P&T committee, those requirements must be met as well.

Comment: A few commenters requested that CMS delay the effective date to at least January 1, 2025, citing the administrative burden associated with forming and operationalizing a committee, as well as the requirement to review all UM policies and procedures. One commenter expressed concern that the requirement to review all policies by January 1, 2024, will result in "good" policies being discarded and cause confusion among providers and enrollees. The commenter suggested that policies should remain active during the review period and be reviewed in accordance with the transparent processes. Some commenters requested CMS delay the implementation date to 2026 to better align with the requirements in the Interoperability rule (87 FR 76238).

Response: CMS declines these suggestions. We are finalizing the proposal that beginning on and after January 1, 2024, MA plans may not use any policies that have not been reviewed or approved by the UM committee established for the plan. Any policy that has not been reviewed or approved by the deadline may not be used by the MA plan until it has been reviewed (and revised as necessary) and approved by the UM committee. Because plans are permitted to leverage existing committees, and some plans indicated they already had committees in place serving a similar function to what was proposed (for example, when required by an, accrediting organization and P&T committees established to review utilization management associated with covered drugs), we believe there is sufficient time for MA organizations and MA plans to form UM committees and review UM policies within the proposed timeframe. Further, § 422.111(d) permits MA plans to change plan rules (including prior authorization and utilization management policies) during the plan year. To make mid-year changes, MA plans must provide a minimum 30-day notice to enrollees, submit the notice to CMS for review, and comply with the model notice specified at § 422.2267(e)(9). This means that if an MA plan's UM committee reviews policies and approves them on a rolling basis, the reviewed and approved policies can be issued during the plan year even if all the reviews are not complete before January 1, 2024.

Comment: CMS solicited comment regarding whether to require UM committees to ensure that the UM policies and procedures are developed in consultation with contracted providers. Numerous commenters supported this requirement. One commenter requested that if UM policies are required to be developed in consultation with contracted providers, the regulation also include a provision that acknowledges MA organizations may not receive responses from providers, therefore an attempt to engage will meet the requirement.

Response: CMS appreciates the feedback received and will take it into consideration for future rulemaking. We encourage MA plans to work with contracted providers while developing UM policies and procedures, and remind plans that under § 422.202(b)(2), MA organizations

must communicate information about practice guidelines and UM policies to providers and, when appropriate, to enrollees.

Comment: Many commenters stated they would be supportive of requiring an UM committee to ensure, as required by § 422.202(b)(2), that an MA organization communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees. One commenter suggested amending § 422.202(b)(1)(iii) to state MA plan practice guidelines and UM guidelines "must be developed in consultation with contracting physicians or practitioners."

Response: CMS thanks all commenters for their input. CMS will continue to monitor compliance with the existing obligations under § 422.202(b) and with § 422.137 as finalized and consider this requirement for future rulemaking. We believe the request to amend § 422.202(b)(1)(iii) is outside the scope of this proposal and that the existing requirements on this issue and on incorporating adequate information about clinical practices are sufficient in light of other amendments in this final rule regarding coverage criteria, medical necessity determinations and use of utilization management policies.

Comment: Many commenters were supportive of a requirement for the UM committee to have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies. A few commenters expressed concern that this requirement could be administratively burdensome on the UM committee. One commenter suggested that the UM committee be required to engage in internal oversight of plan operations, including randomized audits, assessment of rates of and reasons for denial, and duration of time between denials issued. Another commenter suggested that the UM committee review appealed cases and caseloads to determine whether MA plan operations are complying with the relevant requirements so as to not unduly burden provider, MA plan, and the Office of Medicare Hearings and Appeal resources through unnecessary appeals. Another commenter suggested the UM committee conduct

retroactive review of organization determinations throughout the year and assess whether the approved practice guidelines and UM policies are being followed. Another commenter suggested a regulatory revision that would require the UM committee to "…undertake appropriate diligence and oversight to ensure that the MA plan's coverage or medical necessity decisions under any UM policy are consistent with such policy and any revisions to it made by the UM committee." One commenter suggested revising proposed § 422.137(d)(1)(i) to read as follows: "The services to which the utilization management applies, including the total number of cases or requests reviewed under a specific policy being reviewed, the number of approvals for cases or requests under such policy, the number of denials for cases or requests under such policy, and a review of a subset of patient determinations whose cases were denied under such policy, based on the most recent 6 months of data and information available."

Response: CMS appreciates the feedback received and will take it into consideration for future rulemaking. Because MA plans are required to follow the relevant coverage criteria and other requirements pertaining to the use of utilization management adopted in this rule, CMS does not believe it is necessary to require the UM committee to have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies at this time. CMS encourages MA plans to involve the UM committee in such decisions to the extent practicable.

Comment: Several commenters expressed concern over how proposed § 422.137 will be enforced, as well as who will be responsible for enforcement. One commenter suggested that CMS require regular submission of committee determinations and associated documentation to CMS to allow for CMS audit and oversight. Another commenter suggested CMS conduct ongoing audits throughout the year to ensure decisions made by the MA plan are in line with the final approved guidance from the UM committee

Response: CMS currently monitors MA plan compliance through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations

alert CMS to any issues with access to care and plan compliance, and CMS may require MA plans to address these matters if they arise. We intend to use these oversight operations to ensure MA organizations comply with the final rule. Further, § 422.137(d)(5) requires the UM committee to document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request. CMS may request and review such documentation as part of its monitoring and oversight.

Comment: CMS solicited comment regarding whether the proposed regulation text sufficiently and clearly establishes the standards and requirements discussed in the proposed rule. A few commenters requested that the regulations should establish a clear process to ensure transparency with stakeholders, including posting detailed meeting minutes and policies to websites, making the composition of the committee available to the public, and mandating regularly scheduled meetings. Additionally, several commenters requested that there be an opportunity for the public to provide input and comment on UM policies and procedures to ensure transparency and clinician engagement. Several commenters suggested that the UM committee be required to meet and/or review and revise UM policies and procedures more frequently than annually. One commenter suggested that the committee be required to revise UM policies and procedures "at any time." Another commenter stated that policies should remain active during the review period. A few commenters suggested that the UM committee participate in the development of UM policies and procedures. One commenter suggested that the UM committee conduct quarterly or bi-annual reviews of UM policies and programs and their effects on organizational determinations, patient access and clinical validity. One commenter suggested the committee annually update its list of novel therapies and make available to the public the clinical literature and research linked to treatment criteria. A few commenters suggested that CMS revise the regulatory text to require that the clinical members of the UM committee be "appropriately licensed and skilled physicians or other qualified health care providers" opposed to "practicing physicians."

Response: CMS appreciates the feedback received. While § 422.137, as proposed and finalized, requires that prior authorization policies and procedures be reviewed and approved at least annually by the UM committee, the regulation does not prescribe the frequency with which the committee is required to meet or prohibit UM committees from reviewing policies more frequently to address changes in clinical guidelines, coverage criteria, or similar considerations. CMS believes there is value is giving flexibility to UM committees to review UM polices more frequently than once a year, and acknowledges that more frequent meetings are likely warranted. The minimum requirement is that the relevant policies be reviewed and approved annually. We intend to take the feedback from commenters into consideration for future policy development.

Comment: Several commenters addressed the documentation requirements for the UM committee, including that the UM committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request. Several commenters requested that the regulation establish a clear process to ensure transparency with stakeholders, including posting detailed meeting minutes and policies to websites, and making the composition of the committee available to the public. Commenters also stated that MA plans do not regularly release minutes from P&T meetings in a timely manner, and that when these minutes are released, they do not contain detailed information. Several commenters requested that CMS require UM criteria documents to be publicly posted. One commenter requested that such documents should not be required to contain a detailed summary of each piece of evidence considered or rationale for adopting the policy due to potentially containing proprietary information.

Response: CMS thanks commenters for their feedback. As outlined in the preamble, MA organizations must make relevant documentation available to CMS upon request. The documentation should provide CMS with an understanding of the UM committee's rationale for their decision, and may include, but is not limited to, information such as meeting minutes outlining issues discussed and any relevant supporting documentation. Supporting

documentation could include relevant coverage criteria that comply with § 422.101 that was relied on in the decision-making process. As to P&T committee documentation, § 422.136(b)(9) requires that MA plan P&T committees document their decisions regarding the development and revision of step therapy programs and to make that documentation available to CMS upon request; we appreciate the commenter's concerns that information is not always made available publicly or with regularity. Should an MA organization use a P&T committee to fulfill the requirement of the UM committee, that committee must meet all of the requirements outlined in § 422.137, which includes the requirement to make documentation available to CMS upon request. We will consider these comments for future rulemaking.

Comment: Many commenters supported implementing a requirement for the UM committee to review all internal coverage criteria used by the MA plan. Some commenters expressed opposition to the proposal and to any requirement that the UM committee review all internal coverage criteria used by the MA plans, citing that many MA plans have separate committees tasked with reviewing UM policies and coverage criteria. One commenter requested clarification as to which policies and procedures the UM committee is required to review.

Response: Per § 422.137(d), as proposed and finalized, the UM committee is responsible for reviewing UM policies and procedures used by the MA plan(s) served by the committee. The UM Committee must approve only UM policies and procedures that use and are consistent with the relevant coverage criteria that comply with § 422.101 and other applicable regulations. In addition, the UM committee is charged with making any needed revisions to such policies and procedures to ensure that the standards in § 422.137(d)(1) and (2) are met. Such revisions should be made expeditiously when inconsistencies are identified.

Comment: Some commenters requested flexibility in the requirements regarding the composition of the UM committee, specifically the requirement that the committee include various clinical specialties, because of potential operational challenges, including that the conflict of interest requirement be removed. Many commenters requested that specific provider

types be explicitly required for the committee, including but not limited to: Nurse practitioners; physical therapists; chiropractors; integrative medicine providers; pharmacists; clinicians with skilled nursing facility experience; nonphysician care team members; and case management professionals. A few commenters suggested that physician committee members be members of the American College of Physician Advisors, board certified through board of medical specialists or American Board of Medical Specialties. Many commenters supported the inclusion of an enrollee representative. One commenter suggested that more than one provider should be free from conflict, and another commenter suggested that members should have to annually attest to being free from conflict.

Response: CMS appreciates the feedback received and will take it into consideration for future rulemaking. We believe the proposed composition requirements are sufficient because they represent a diverse group of medical professionals, with the relevant expertise necessary to fulfil the regulatory requirements. Requiring additional specific provider types or specialties could end up limiting the committee composition, and that there is value in allowing plans the flexibility to determine which providers should be represented. Further, § 422.137(c)(4) requires that the committee include members representing various clinical specialties to ensure that a wide range conditions are adequately considered in the development of the MA plan's utilization management policies. We believe this requirement will ensure that a diverse range of specialists are represented. Section 422.137(c)(2) requires that *at least* one physician be independent from the MA plan and free of conflict. We believe this is sufficient because the other requirements for the UM committee clearly establish the parameters in which the UM committee must review and approve UM policies and procedures, and therefore additional independent committee members are not necessary to ensure appropriate decisions are being made. We encourage plans to include an enrollee representative on the UM committee as we believe enrollee representation will add a valuable perspective to the review process.

Comment: Many commenters supported having a specialist with expertise in the particular item or service that is subject of the UM policy and procedure under review by the UM committee be involved in that review. A few commenters suggested that there should be specialty-focused subcommittees or workgroups to ensure appropriate expertise is represented. One commenter suggested that the UM committee be required to seek outside assistance when the committee does not have expertise in a certain area.

Response: CMS appreciates the feedback received and will take it into consideration as part of future policy development. We believe that the requirements in § 422.137(d)(1) and (2) that set the standards for the review by UM committees, including that utilization management policies comply with § 422.101(b) (which includes compliance with Traditional Medicare coverage rules and limits on MA plan internal coverage criteria) and that the committee review relevant current clinical guidelines, are sufficient to ensure that appropriate evidence is reviewed and relied upon by the committee during its annual (or more frequent) review of utilization management policies. Therefore, we are not adopting an additional requirement for the UM committee to have specialty focused subcommittees and workgroups.

We are not finalizing an additional requirement for participation or involvement by a specific specialty provider or health care provider with expertise related to each individual UM policy. We believe that is unnecessary because, as previously noted, all utilization management policies must comply with § 422.101(b), which requires any permissible internal coverage criteria must be based on current evidence in widely used treatment guidelines or clinical literature. 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. Therefore, we do not believe it is necessary for additional involvement of specialists when reviewing utilization management policies and procedures. CMS encourages plans to include relevant experts when feasible during the review process.

Comment: One commenter requested clarification on the definition of "practicing physician who is an expert regarding care of elderly or disabled individuals."

Response: CMS considers someone an expert who, per the dictionary definition of "expert," [116] has special skill or knowledge derived from training or experience; here that level of skill or knowledge must be in the area of providing care for elderly or disabled individuals. Because the UM policies under review by the committee will be used for coverage and services furnished to Medicare beneficiaries, it is critical to ensure that a provider with knowledge relevant to the population eligible for enrollment in the MA plan (that is, Medicare enrollees) is represented on the UM committee. We encourage MA organizations that offer SNPs to include providers with experience and expertise related to the special needs of the enrollees served by the SNP.

Comment: A commenter suggested that the UM committee be required to review any prior authorization policies used by the MA organization, including those developed and managed by third party entities. Another commenter requested clarification as to how proposed § 422.137 would apply when an MA plan has delegated utilization management functions, including whether and how the requirements of proposed § 422.137 would be shared or divided between the MA plan and its delegate(s)

Response: Per § 422.138 as proposed and finalized, the UM committee is required to, at least annually, review the policies and procedures for all utilization management, including prior authorization, used by the MA plan. This means that any UM policy or procedure that is used by the plan, whether developed or managed by a third-party entity, must be reviewed and approved by the UM committee.

Comment: A few commenters requested that CMS not require a committee to review and approve all UM policies and procedures.

[116] https://www.merriam-webster.com/dictionary/expert

Response: CMS declines this suggestion. For the reasons outlined in the proposed rule and our responses to other comments and in light of feedback CMS has received and concern that enrollees may be facing unreasonable barriers to needed care, CMS believes ensuring UM policies and procedures are reviewed on a timely and consistent basis to ensure that the UM policies meet minimum standards is of paramount importance.

Comment: A commenter supported involving the UM committee in developing mechanisms to address system vulnerabilities. Another commenter suggested revise § 422.137(d) to require the UM Committee to review data on manual review errors, system errors, and excessive denials, to revise UM policies and procedures as appropriate to reduce the risk of such errors, and to identify and implement system changes to mitigate the risk of manual review errors and system errors.

Response: CMS thanks the commenters for their comment. At this time, we decline to make these revisions and are finalizing as proposed. We will consider these suggestions in future rulemaking.

We thank all commenters for their comments. After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments, as previously summarized, we are finalizing the new regulation § 422.137 and the modification to § 422.202(b)(1)(i) as proposed.

6. Additional Areas for Consideration and Comment

CMS solicited comment on three areas: (1) termination of services in post-acute care, (2) gold carding, and (3) addressing vulnerabilities that can lead to manual review errors and system errors. Since no regulations were proposed, we are not finalizing anything in these areas at this time. We thank commenters for their input, and will consider all comments during future rulemaking.