

serve as a basis for SEP eligibility. One commenter requested that CMS expand the SEP for Significant Change in Provider Network at § 422.62(b)(23) so that it would be available to any plan enrollee who wishes change plans mid-year in order to continue to see their provider(s). Another commenter requested that CMS create a new SEP for any enrollee whose provider is terminated, stating that such an event is a common, not unique, event that should not need to be reviewed on a case-by-case basis. This commenter requested that the new SEP be three months in length and be available to any enrollee who receives a notice of provider termination sent in accordance with § 422.111(e).

Another commenter requested that CMS take the position that that any enrollee who has ever received care from a particular provider or facility is eligible for an SEP upon termination of that provider or facility, including an enrollee who attests to having confirmed a provider's or facility's in-network status when making a decision to join the MA plan.

One commenter who expressed opposition to offering an SEP to an enrollee who is impacted by a provider contract termination stated that an enrollee should not be eligible for an SEP if other providers are available in the network. Another stated that notifying enrollees of a potential SEP may create confusion when a provider retires and there are other providers available in the network.

Response: We appreciate the commenters' support for our proposal to consider an enrollee who is impacted by a provider contract termination to be someone who is experiencing an exceptional condition and therefore eligible for the SEP specified in § 422.62(b)(26). We also appreciate the response to our solicitation for feedback on alternative approaches, such as the adoption of a new SEP for this type of provider contract termination. We did not propose any changes to the SEPs at §§ 422.62(b)(23) and 422.62(b)(26), so this final rule will not include any changes to these regulations; however, we will consider this feedback in future rulemaking and policy development.

Summary of Regulatory Changes

We received a range of comments pertaining to this proposal, the majority of which reflected support for the regulations. After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed changes to

§ 422.111(e) with the following modifications:

- In proposed regulation text § 422.111(e)(1)(i), we are removing the phrase “both written and telephonic notice” and adding the phrase “written notice and make one attempt at telephonic notice to those enrollees identified in paragraph (e)(1)(iii) of this section who have not opted out of calls regarding plan business as described in § 422.2264(b).” Thus, we are revising (e)(1)(i) to read as follows: “Provide written notice and make one attempt at telephonic notice to those enrollees identified in paragraph (e)(1)(iii) of this section who have not opted out of calls regarding plan business as described in § 422.2264(b).”

- In proposed regulation text § 422.111(e)(1)(iii), we are adding the phrase “are currently assigned to that primary care provider and to enrollees who” and removing the word “ever” and adding the phrase “within the past three years.” Thus, we are revising (e)(1)(iii) to read as follows: “To all enrollees who are currently assigned to that primary care provider and to enrollees who have been patients of that primary care or behavioral health provider within the past three years.”

We are finalizing changes to § 422.2267(e)(12) as proposed.

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 report⁹⁵ titled, “Some Medicare

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>.

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 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 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

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

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 study⁹⁷ 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 studies⁹⁸ 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 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

⁹⁷ <https://www.fda.gov/media/78504/download>.

⁹⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/>.

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 placement¹⁰⁰ 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. 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

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>.
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-2009andStrengthofRecommendationTaxonomy> <https://www.jabfm.org/content/17/1/59#F1>).

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 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 below.

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 guidance¹⁰² 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 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

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

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 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

¹⁰³ <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCID=176>

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 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.

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

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 utilization 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 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

¹⁰⁵ <https://cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=373>.

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