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Medicare Advantage: CMS Issues FAQs to Further Clarify New Regulations

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On February 6, 2024—almost a year after publishing a sweeping final rule amending Medicare Advantage (MA) regulations and clarifying prior guidance—the Centers for Medicare & Medicaid Services (CMS) issued a set of Frequently Asked Questions (FAQs) to explain how it expects MA plans to comply with the new regulations.[1] Release of these FAQs coincides with the publication of CMS' Interoperability and Prior Authorization Final Rule (CMS-0057-F),[2] as CMS signals a continued focus on MA plan compliance with Medicare coverage rules and ensuring timely access to care for MA enrollees.

This article provides an overview of the highlights set forth in the FAQs.[3]

Use of Algorithms and Other Forms of Artificial Intelligence

Preamble commentary to the Final Rule made no mention of artificial intelligence and just a single reference to use of algorithms by MA plans in making medical necessity determinations.[4] In that single reference, CMS stated that "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."[5]

In the FAQs, CMS clarified that while MA plans may use algorithms or software tools in making coverage determinations, they must "ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made."[6] The FAQs further clarify that medical necessity determinations must be based on the enrollee's particular circumstances, medical history, physician recommendations, and clinical notes.[7] Thus, while MA plans may use an algorithm or other software tool to assist in predicting a potential length of stay in the context of post-acute care, "that prediction *alone* cannot provide the basis to terminate post-acute care services."[8] Likewise, as it relates to inpatient admissions, use of algorithms or artificial intelligence *alone* cannot serve as the basis to deny admission or downgrade an admission to an observation.[9]

CMS went on to remind MA plans of the nondiscrimination requirements set forth in the Affordable Care Act, noting concern that algorithms or other forms of artificial intelligence "can exacerbate discrimination and bias."[10] This noted concern is consistent with other proclamations by the Biden Administration regarding the potential for bias and discrimination in artificial intelligence.[11]

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CMS' FAQ on the use of artificial intelligence is timely given that multiple MA plans are facing class action lawsuits for allegedly using artificial intelligence to inappropriately deny care to enrollees.[12] Use of predictive analytics based on algorithms and other forms of artificial intelligence will surely continue to be a hotly discussed and debated issue as the capabilities of these technologies evolve.

Internal Coverage Criteria

CMS also issued several FAQs regarding the provisions of the Final Rule that regulate MA plans' use of internal coverage criteria.

Under the Final Rule, MA plans may create "publicly accessible" internal coverage criteria only when coverage criteria are "not fully established in applicable Medicare statutes, regulations, NCDs or LCDs."[13] Moreover, when an MA plan seeks to create such criteria, it must demonstrate that the additional criteria provide clinical benefits that are "highly likely" to outweigh any clinical harms.[14]

CMS clarified in the FAQs that "publicly accessible" means that the information must be available to the entire public—not just plan enrollees or contracted providers.[15] Additionally, while requiring one or two basic pieces of information to gain access to the internal coverage criteria may not undermine public access, CMS suggested that "overly burdensome information collection in order to gain access" would be inconsistent with the regulation.[16]

Using an example of an existing National Coverage Determination (NCD), CMS also elaborated on how it expects MA plans to demonstrate that the clinical benefits of internal coverage criteria are highly likely to outweigh any relative clinical harm.[17] According to the FAQs, MA plans must offer a public explanation that "systematically explain[s]" the relative clinical benefits and harms.[18] CMS added that any internal coverage criteria should be "narrowly tailored" to a particular patient population—not just all patients for whom an item or service is ordered.[19]

Notably, CMS clarified that MA plans are not exempted from these requirements by using coverage criteria contained in a Local Coverage Determination (LCD) adopted by a Medicare Administrative Contractor (MAC) outside of the MA plan's service area.[20] Therefore, if an MA plan seeks to use the coverage criteria adopted by a MAC outside of the plan's jurisdiction, the plan must still follow the coverage requirements set forth in the Final Rule, including ensuring that the criteria is based on current, widely-used evidence and making the criteria publicly available.[21]

CMS warned multiple times throughout the FAQs that it will monitor plan compliance with the new regulations and may issue additional guidance if necessary to ensure compliance.[22]

The Two-Midnight Rule

CMS adopted the two-midnight rule (Rule) for Traditional Medicare inpatient admissions beginning on or after October 1, 2013, and updated the Rule in 2015 in response to significant questions (and pushback) from the provider community including concerns about the Rule's impact on clinical care.[23] The Rule addressed many years of disputes about when CMS would consider an inpatient admission to be medically necessary under Medicare Part A, as opposed to care that might be more appropriately provided on an outpatient basis under Part B. Depending upon how the MA plan is structured, the patient's status as inpatient or outpatient may impact payments to providers, patient co-pays and deductibles, and qualifying stays for post-acute skilled nursing facility services (as it does for Traditional Medicare).

Section 412.3(d)(1) currently provides that:

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> Except as specified in paragraphs (d)(2) and (3) of this section, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.

Section (d)(2) relates to inpatient only procedures; section (d)(3) relates to expectations for physician documentation for admissions that do not cross two midnights.

In the Final Rule, CMS confirmed the applicability of 42 C.F.R. § 412.3 to MA inpatient admissions, while acknowledging that Section 412.3 is a payment rule for Traditional Medicare [Part 412 is titled "Prospective Payment Systems for Inpatient Hospitals"].[24] According to the Final Rule, "it is irrelevant whether Traditional Medicare considers the criteria part of a coverage rule or a payment rule, as both address the scope item and services for which benefits are available to Medicare beneficiaries under Parts A and B."[25]

In addition, CMS distinguished between (1) the two midnight benchmark, which specifies when inpatient admissions will be considered covered by CMS, and (2) the two midnight presumption, which is in essence an audit approach where Traditional Medicare contractors do not look behind the orders of the treating physician that inpatient care is medically necessary and reasonable if the two midnight benchmark applies, which does not apply to MA plans.

Question 8 of the FAQs is "[d]oes the CY 2024 final rule mean that MA organizations [MAOs] must follow the Medicare 'two-midnight rule'?" The answer, in short, is "sometimes." More specifically, the "presumption" arises from Traditional Medicare audit approaches that may or may not be translated to particular MA claims but is not intended to limit or disrupt the MAO's use of its own internal scrutiny processes to review the claims. With respect to the "benchmark," however, this is considered presumptive admission criteria that the MAO must follow.

As summarized by CMS in the FAQ answer,

> The term 'two-midnight rule' is sometimes used to describe different things: either the "two-midnight presumption" or the "two-midnight benchmark" admission criteria. As explained further below, MA plans do not have to follow the "two-midnight presumption," which relates to medical review instructions for contractors in Traditional Medicare. However, another colloquial use of the term "two-midnight rule" is to describe the inpatient admission criteria in 42 C.F.R. § 412.3, which include a "two-midnight benchmark;" MA plans are required to follow these inpatient admission criteria.

The FAQ also repeats CMS' position that it will respect the decision of the treating physician as to what level of care the patient needs—with the caveat of reasonableness. "Consistent with § 412.3, that evaluation [of coverage for inpatient services] should defer to the judgment of the physician as long as that judgment was reasonable based upon the complex medical factors documented in the medical record."

Prior Authorization

In 2022, addressing a concern about the "potential incentive . . . to deny beneficiary access to services and deny payments to providers in an attempt to increase profits," the Department of Health and Human Services Office of Inspector General (OIG) issued a report that identified significant concerns about the MAO's use of prior authorization processes.[26]

In the Final Rule, CMS similarly noted that it had received feedback that utilization management in MA plans, especially prior authorization practices, could sometimes create a barrier to patients accessing medically necessary care.[27] CMS stated that "[s]imilar to [Medicare Administrative Contractors] in Traditional Medicare, we expect

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MA organizations to make medical necessity decisions based on NCDs, LCDs, and other applicable coverage criteria. . . to determine if an item or service is reasonable, necessary, and coverable under Medicare Part A or Part B."[28] As discussed above, the MA plan may still apply utilization management practices, but must limit the coverage criteria used to deny coverage for an item or service so as to make accessible the basic Medicare benefits it is required to offer.

FAQ number 11 asks, "[c]an MA plans still use prior authorization and how does the CY 2024 final rule impact the use of prior authorization?" CMS responds that reliance upon a requirement for prior authorization is still permissible, except in certain limited circumstances. CMS then goes on to summarize several provisions relating to prior authorization that were included in the Final Rule (effective January 1, 2024), including:

- Prior authorization may only be used by MA coordinated care plans to confirm the presence of diagnoses or other medical criteria, to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically appropriate (§ 422.138(b)). Therefore, prior authorization should not function to delay or discourage care.

- For MA coordinated care plans, approval of a prior authorization request for a course of treatment must be valid for as long as medically reasonable and necessary to avoid disruptions in care in accordance with applicable coverage criteria, the patient's medical history, and the treating provider's recommendation. Further, MA coordinated care plans must provide a minimum 90-day transition period for new enrollees, during which the new MA plan may not require prior authorization for any active course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider (§ 422.112(b)(8)).

- To ensure prior authorization is being used appropriately, all MA plans must establish a Utilization Management Committee to annually review utilization management policies and ensure consistency with Traditional Medicare's national and local coverage decisions and guidelines (§ 422.137).

The FAQ also notes the importance of timeliness with respect to prior authorization decisions.

Conclusion

MA plans now cover more than 50% of the Medicare population.[29] With this dramatic increase in MA's role in the coverage, delivery and payment of services to Medicare beneficiaries, as well as concerns identified by OIG and relators, it is to be expected that scrutiny of the MA programs will increase. CMS' 2023 Final Regulations set forth significant statements of policy to guide MAOs as to their expectations for plan performance on several important topics (only some of which are discussed in this summary). The FAQs provide additional interpretive subregulatory guidance to explain and provide further direction on the issues addressed in the Final Regulations.

[1] CMS, *Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)* (Feb. 6, 2024) (hereinafter "CMS FAQs"); *see also* 88 Fed. Reg. 22120 (Apr. 12, 2023).
[2] 89 Fed. Reg. 8758 (Feb. 8, 2024).
[3] For an overview of the Final Rule, see a previous article published in AHLA's Health Law Weekly. *See* Judith A. Waltz & Alexandra B. Shalom, *Medicare Advantage: 2023 Final Rule Focuses on Social Determinants of Health and Utilization Review* (Apr. 14, 2023).
[4] *See* 88 Fed. Reg. at 22195.
[5] *Id.*

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[6] CMS FAQs.
[7] *Id.*
[8] *Id.* (emphasis added).
[9] *Id.*
[10] *Id.*
[11] *See, e.g.*, DOJ Press Release, *Justice Department's Civil Rights Division Joins Officials from CFPB, EEOC and FTC Pledging to Confront Bias and Discrimination in Artificial Intelligence* (Apr. 25, 2023), https://www.justice.gov/opa/pr/justice-department-s-civil-rights-division-joins-officials-cfpb-eeoc-and-ftc-pledging.
[12] https://www.cbsnews.com/news/unitedhealth-lawsuit-ai-deny-claims-medicare-advantage-health-insurance-denials/; https://www.cbsnews.com/news/health-insurance-humana-united-health-ai-algorithm/.
[13] 88 Fed. Reg at 22122; 42 C.F.R. § 422.101(b)(6).
[14] 88 Fed. Reg at 22122; 42 C.F.R. § 422.101(b)(6)(i)(a).
[15] CMS FAQs.
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] https://www.cms.gov/newsroom/fact-sheets/fact-sheet-two-midnight-rule.
[24] 88 Fed. Reg. at 22191.
[25] *Id.*
[26] Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. OEI-09-18-00260 (4-27-2022), https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp.
[27] 88 Fed. Reg. at 22185.
[28] 88 Fed. Reg. at 22188.
[29] https://www.kff.org/policy-watch/half-of-all-eligible-medicare-beneficiaries-are-now-enrolled-in-private-medicare-advantage-plans/#.

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