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CMS implements new regulations to restrict Medicare Advantage organizations

by Kristen Dobson

As the number of Medicare enrollees choosing Medicare Advantage (MA) over traditional Medicare has steadily increased over the past decade and a half, healthcare providers have been sounding the alarm with Centers for Medicare & Medicaid Services (CMS) about MA organizations (MAOs) inappropriately delaying and denying coverage of medically necessary care. (As of last year, the share of eligible Medicare beneficiaries enrolled in MA has more than doubled since 2007.)[1] Last year, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued a report that echoed those concerns, finding that MAOs sometimes delay or deny care even when that care meets traditional Medicare coverage rules.[2]

OIG further found that MAOs often denied prior authorization requests that met Medicare coverage rules by using clinical criteria not contained in Medicare rules and requiring unnecessary documentation to support the medical necessity of the services. In many of these cases, OIG found that the clinical information in the case file was already sufficient to demonstrate the medical necessity of the services requested.[3] Based on its findings, OIG made several recommendations to CMS, including recommending that CMS "issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews."[4]

Earlier this year, CMS issued new regulations aimed at addressing some of these issues.[5] Based on the OIG report and the feedback it received from stakeholders, CMS 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."[6]

Most notably, the new rules clarify that:

- MAOs must comply with general coverage and benefit conditions set forth in traditional Medicare laws when making coverage decisions and medical necessity determinations;
- The two-midnight rule, and the admissions criteria set forth in 42 C.F.R. § 412.3, apply to MAOs; and
- Prior authorizations should be used only to confirm the presence of diagnoses or other medical criteria and ensure that the furnishing of a service or benefit is medically necessary. Additionally, prior authorizations must be valid for an entire course of approved treatment.

While the new rules are a good start for addressing many of the systemic issues providers have encountered with MAOs for years, it remains an open question regarding how they will be enforced. With respect to the new prior

authorization requirements, CMS declined one commenter's suggestion to develop a process for providers to report when MAOs fail to follow the rules, noting that CMS currently monitors MAOs' compliance with existing policies and will continue to do so to ensure compliance with the new regulations.[7]

Therefore, providers should familiarize themselves with these new rules to ensure they can effectively hold MAOs accountable. These new regulations—coupled with statements made by CMS in preamble commentary to the surprise billing rules issued in 2021—offer useful points for providers to argue when challenging unsupportable and unreasonable denials from MAOs.

MAOs are bound by traditional Medicare rules when making coverage and medical necessity determinations

As part of the new rules, CMS clarified once and for all that MAOs must cover all Medicare Parts A and B benefits on the same conditions that items and services are furnished in traditional Medicare.[8] Therefore, when making coverage decisions, MAOs must comply with general coverage and benefit conditions included in traditional Medicare laws. The new rules further clarify that medical necessity determinations by MAOs must be based on the enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.[9] CMS amended 42 C.F.R. § 422.101 to reflect these now explicit standards.

CMS further explained that MAOs must comply with national coverage determinations (NCDs), local coverage determinations (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 Parts A or B.[10] While MAOs have flexibility to furnish and cover services without meeting all substantive conditions of coverage in traditional Medicare, the new rules clarify that such flexibility is limited to *supplemental* benefits.[11] This means that MAOs may not limit coverage through the adoption of policies and procedures that result in denials of coverage or payment where the traditional Medicare program would cover and pay for the item or service.

CMS elaborated on this requirement in the preamble commentary to the new rules, explaining that an MAO may deny a request for Medicare-covered, post-acute care services in a particular setting *only if* the MAO determines that the traditional Medicare coverage criteria for the services cannot be satisfied in that particular setting.[12] If care can be delivered in more than one way or more than one type of setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MAO may deny coverage of the services or setting *only if* the ordered services do not meet coverage criteria. In other words, if an MA patient is being discharged from an acute care hospital and the attending physician orders post-acute care at a skilled nursing facility (SNF) because the patient requires skilled nursing care on a daily basis in an institutional setting, the MAO cannot deny coverage for SNF care and redirect the patient to home healthcare unless the patient does not meet the coverage criteria for SNF care.[13]

The new rules further clarify that only when coverage criteria is not fully established in Medicare statute, regulation, NCD, or LCD can an MAO create internal coverage criteria.[14] However, even then, an MAO's internal criteria must be based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available.[15] The new rules further specify 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. Evidence that is unpublished "or derived solely from internal analyses" within the MAO is not sufficient.[16]

In creating these internal policies, MAOs must follow similar rules that CMS and Medicare administrative

contractors (MACs) follow when creating NCDs or LCDs.[17] While CMS did not go so far as to require notice and comment for these policies, the new rules require that MAOs provide publicly available information that discusses the factors the MAO considered in making the criteria, including a summary of the evidence that was considered during the development of the internal coverage criteria, 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.[18] Additionally, when the basis for the internal policy is that coverage criteria is not fully established, the MAO must identify the general provisions that are being supplemented or interpreted and explain how the additional criteria provides clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.[19] If an MAO uses internal criteria to deny coverage of an item or service, the criteria must be clearly stated in the denial notice.[20]

The two-midnight rule applies to MAOs

Although the original proposed rule did not address the applicability of the two-midnight rule to MAOs, it appears CMS had a change of heart after reviewing the more than 1,000 comments timely submitted in response to the proposed rule. In response to several commenters who specifically requested that CMS more clearly state that MAOs must follow the two-midnight rule, CMS confirmed that the admissions criteria set forth in 42 C.F.R. § 412.3, including the two-midnight rule, apply to MAOs.[21] Therefore, an MAO must provide coverage for an inpatient admission when the admitting physician expects the patient to require hospital care that crosses two-midnights when the admitting physician does not expect the patient to require care that crosses two-midnights but determines that inpatient care is nonetheless necessary, and when inpatient admission is for a surgical procedure.[22]

CMS did note, however, that the "two-midnight presumption" (the presumption that all inpatient claims that cross two midnights following the inpatient admission order are "presumed" appropriate and are not the focus of medical review absent other evidence) *does not* apply to MAOs.[23] CMS explained that the two-midnight presumption is a medical review instruction given to MACs and other Medicare contractors to help aid them in the selection of claims for medical necessity review.[24] Thus, the new rules do not dictate how MAOs can decide which claims to subject to review.

Limitations on the use of prior authorizations

CMS also added a new regulation, 42 C.F.R. § 422.138, to specifically address the use of prior authorization by MAOs. With this new regulation, CMS clarified that prior authorizations should be used *only* to confirm the presence of diagnoses or other medical criteria and ensure that a service or benefit is medically necessary or, for supplemental benefits, clinically appropriate and should not function to delay or discourage care.[25]

Under the new regulation, if an MAO approves furnishing a covered item or service through a prior authorization or pre-service determination of coverage or payment, the MAO may not later deny coverage based on lack of medical necessity. The new provision also makes clear that an MAO may not reopen such a decision for any reason except for good cause or if there is reliable evidence of fraud or similar fault in accordance with the reopening provisions codified in 42 C.F.R. § 422.616.[26]

To help illustrate how these prior authorization policies should work, CMS used an existing NCD as an example. NCD 30.3.3 (acupuncture for chronic lower back pain) authorizes acupuncture for patients with chronic lower back pain for up to 12 visits in 90 days if the pain lasts 12 weeks or longer, is nonspecific—in that it has no identifiable systemic cause (that is, not associated with metastatic, inflammatory, infectious disease, etc.)—is

not associated with surgery, and is not associated with pregnancy. In the context of this NCD, CMS explained that an MAO may require prior authorization to verify that the patient's pain is not the result of metastatic, inflammatory, infectious disease, as specified in the NCD.[27] CMS clarified, however, that if the MAO approves this service through prior authorization, it may not later deny coverage based on a lack of medical necessity.

In response to complaints about interruptions in treatment, CMS also amended 42 C.F.R. § 422.112 to require that approval of a prior authorization request for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care.[28]

Although some commenters requested that CMS do more to prohibit the use of prior authorization, CMS asserted that it does not have the authority to implement a sweeping prohibition on all use of prior authorizations.[29] CMS also declined to require MAOs to make prior authorization criteria publicly available, noting that the existing regulation at 42 C.F.R. § 422.111(b)(7) already requires MAOs to disclose to enrollees any prior authorization rules and other review requirements that must be met to ensure payment for the services.[30] CMS, likewise, noted that the existing regulation at 42 C.F.R. § 422.202(b)(2) requires MAOs that use a network of providers to communicate practice guidelines and utilization management guidelines to providers and, as appropriate, enrollees.[31]

Additional resources for providers fighting denials

In addition to these new MA rules, CMS has issued a series of regulations over the last two years as part of its implementation of the No Surprises Act. Within the preamble commentary, there is useful language on those regulations that providers can reference when facing denials from MAOs.

In preamble commentary to the Requirements Related to Surprise Billing; Part I Final Rule, CMS denounced the practice of some plans and payers to deny coverage of emergency services based solely on final diagnosis codes without regard to the individual's presenting symptoms or any additional review, stating that such a practice is inconsistent with the No Surprises Act and the Affordable Care Act.[32] CMS made clear that the prudent layperson standard applies and the determination of whether the standard is met must be based on all pertinent documentation and be focused on the presenting symptoms (and not solely on the final diagnosis).[33]

Conclusion

CMS's new regulations provide much-needed support to healthcare providers facing phantom criteria and policies imposed by MAOs, resulting in denying essential services that would not have been questioned under traditional Medicare. Although these new regulations do not address all issues encountered by providers with MAOs, the good news is that the government does not seem to be relaxing its stance on this matter. In May, the United States Senate Permanent Subcommittee on Investigations held a hearing on "Examining Health Care Denials and Delays in Medicare Advantage." Officials from OIG and the Kaiser Family Foundations Program provided testimony on Medicare policy and addressed the concerns and challenges related to MA.

Takeaways

- Medicare Advantage organizations (MAOs) must comply with general coverage and benefit conditions in traditional Medicare laws, including national coverage determinations and local coverage determinations, when making coverage and medical necessity determinations.
- MAOs can create internal coverage criteria only when coverage criteria are not fully established in Medicare regulations. MAOs must follow specific rules when creating internal criteria.

- The "two-midnight" rule applies to MAOs.
- Prior authorizations can be used only to confirm the presence of diagnoses or other medical criteria and to ensure that a service is medically necessary.
- Prior authorizations must be valid for an entire course of approved treatment.

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3 Grimm, *Some Medicare Advantage Organization Denials.*
4 Grimm, *Some Medicare Advantage Organization Denials.*
5 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 82 Fed. Reg. 22,120 (Apr. 12, 2023), https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf.
6 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,186.
7 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,203.
842 C.F.R. § 422.101(a).
9 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,199.
10 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,188.
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14 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,128, 22,189.
15 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,188–89.
16 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,188–89.
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18 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,188–89.
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25 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,200.
26 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,203.
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31 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, 82 Fed. Reg. at 22,202.
32 Requirements Related to Surprise Billing; Part I, 86 Fed. Reg. 36,872, 36879 (July 13, 2021), https://www.govinfo.gov/content/pkg/FR-2021-07-13/pdf/2021-14379.pdf.
33 Requirements Related to Surprise Billing.