Submitted Electronically via www.regulations.gov

January 27, 2025

Jeff Wu, J.D., M.B.A.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-4208-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Proposed Contract Year 2026 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 (CMS-4208-P)

Dear Acting Administrator Jeff Wu:

INTRODUCTION

The American Association for Homecare (AAHomecare) is the national association representing durable medical equipment (DME), prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. Our members are proud to be part of the continuum of care that assures beneficiaries, and other patients receive cost effective, safe, and reliable home care products and services. AAHomecare thanks CMS for the opportunity to provide comments in response to the Contract Year 2026 Medicare Advantage and Part D Technical Proposed Rule (89 Fed. Reg. 99340, December 10, 2024) ("2026 Proposed Rule").[1] Our comments focus on the proposals that pertain to Medicare Part B DMEPOS suppliers contracted with Medicare Advantage (MA) plans.

COMMENTS

I. Enhancing Rules on 'Internal Coverage Criteria'.

Existing regulations permit MA organizations (MAOs) to create publicly accessible internal coverage criteria. CMS in the 2026 Proposed Rule affirms that an MAO's internal coverage criteria cannot be used to "add new, unrelated … coverage criteria for an item or service that already has existing, but not fully established, coverage policies" under Medicare.

[1] CMS, Contract Year 2026 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 Proposed Rule, 89 Fed. Reg. 99340 (Dec. 10, 2024) ("2026 Proposed Rule").

CMS in the 2026 Proposed Rule proposes to amend 42 C.F.R. § 422.101(b)(6)(i)(A) to "make it explicitly evident that internal coverage criteria may only be used to supplement or interpret already existing" Medicare coverage and benefit rules. CMS proposes to define "internal coverage criteria" to include "any policies, measures, tools, or guidelines, whether developed by an MA organization or a third party, that are not expressly stated in applicable statutes, regulations, NCDs, LCDs, or CMS manuals and are adopted or relied upon by an MA organization for purposes of making a medical necessity determination," noting that CMS manuals are not "internal coverage criteria" for MAOs. CMS proposes to replace the requirement that MA plans 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" with policy guardrails for all internal coverage criteria, including prohibitions against: (1) criteria that do not have clinical benefit, and (2) criteria used to automatically deny coverage of "basic benefits without the MA organization making an individual medical necessity determination as required" by the regulations. Further, CMS proposes that, by January 1, 2026, MAOs must publicly display a list of all Part A and Part B items and services for which the MAO uses internal coverage criteria when making medical necessity decisions.

AAHomecare appreciates CMS's efforts to ensure that MA plans do not arbitrarily deny service based on internal coverage criteria, and we support CMS's proposal to require public disclosure of items and services for which internal coverage criteria are used. As such, we recommend that CMS finalize these proposals. Additionally, we respectfully request that CMS ensure that MAOs comply with all internal coverage criteria requirements, including these enhanced protections, for DME.

Under traditional (fee-for-service, or FFS) Medicare, DME items are covered under the Part B DMEPOS benefit. MA plans must cover benefits available under FFS Medicare; historically, MA plans have covered DME items, such as continuous glucose monitors (CGMs), under their DMEPOS benefit. Additionally, FFS Medicare and MA plans have historically covered CGMs when dispensed by participating DMEPOS suppliers. As discussed below in this letter, AAHomecare is aware of MA plans that interpret CMS policy guidance, such as the Glucose Monitor Policy Article,[2] as not being fully binding on MA plans. In some cases, MA plans interpret the Contract Year 2024 MA and Part D Technical Rule (88 Fed. Reg. 22120, April 12, 2023) ("2024 Final Rule") to only require MA plans to comply with CMS coverage guidelines and manuals to the extent that these policies define the scope and conditions for coverage under FFS.[3] Pursuant to their internal interpretation of CMS coverage requirements, these MA plans enacted policies to limit MA beneficiary access to DME items—specifically, CGMs—by only permitting in-network pharmacies to dispense CGMs, thereby prohibiting DMEPOS suppliers from dispensing CGMs to beneficiaries. AAHomecare is also aware of MA plans interpreting longstanding CMS policy, including the 2000 Medicare + Choice Final Rule (65 Fed. Reg. 40170, June 28, 2000) ("2000 M+C Final Rule"), to permit limiting health service delivery to certain providers.[4] According to these plans, the 2000 M+C Final Rule's assertion that regulations requiring MA plans to cover basic benefits, under § 422.101(a), "is not intended to dictate care delivery approaches for a particular service," allows the plans to restrict which providers can dispense DME items, such as CGMs.[5] These limitations have caused significant disruptions in care for beneficiaries. AAHomecare respectfully

[2] Glucose Monitor – Policy Article, CGS Administrators, LLC and Noridian Healthcare Solutions, LLC (original effective date Oct. 1, 2015), available at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464 (MAC Policy Article, article ID A52464).

[3] CMS, 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, 88 Fed. Reg. 22120 (Apr. 12, 2023) ("2024 Final Rule").

[4] CMS, Medicare Program; Medicare + Choice Program; Final Rule, 65 Fed. Reg. 40170, 40207 (Jun. 28, 2000) ("2000 M+C Final Rule").

[5] *Id.* at 40207.

requests that CMS, in the final rule, explain that MA plans cannot interpret CMS coverage policies in a manner that limits beneficiary access to items and services available under FFS, including DME items.

AAHomecare is also aware of several instances where MA plans have arbitrarily denied coverage for DME items, despite clear Part A and Part B coverage for the items. We respectfully request that CMS exercise its existing authority to limit MA plans' use of internal coverage criteria for DME items when criteria is more restrictive than the equivalent criteria under original (FFS) Medicare.

MA plans often deny coverage for non-invasive ventilator (NIV) coverage based on a Medicare contractor's RAD (respiratory assist device) LCD language, which does not apply to NIV devices. There is not an LCD for NIV; therefore, coverage should be based on CMS's NCD for NIV, which does not mention trying a RAD first and failing to qualify for an NIV device. Furthermore, when NIV is prescribed for lifetime and meets the NCD coverage criteria, MA plans often only approve temporary authorizations and later deny continued authorization requests with the same medical documentation originally submitted. This creates gaps in coverage for medically necessary life-sustaining devices. The prior authorization length should be consistent with the length of need ordered by the physician.

MA plans also often deny beneficiary access to medically necessary accessories and associated electronics on Group 3 complex power wheelchairs. Despite clear coverage requirements, MA plans have not provided access in accordance with CMS policy: MA plans have denied the very items and services that DME MACs cover under the published LCD, associated policy articles, and a "Power Wheelchair Electronics Clarification" article. We therefore respectfully request that CMS use its existing authority to make clear that MA plans cannot reinterpret CMS's clear coverage policies for DMEPOS items.

II. Guardrails for Artificial Intelligence (AI).

In response to the increase in utilization of AI technology in healthcare, and in alignment with key civil rights provisions in the *Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence* (October 30, 2023), CMS in the 2026 Proposed Rule states that "it is necessary to ensure that the use of AI does not result in inequitable treatment, bias, or both, within the healthcare system..." As such, CMS proposes to revise existing regulations under § 422.112(a)(8) "to ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems," and that, if a MA plan uses AI or an automated system, those technologies comply with the anti-discrimination requirements of § 1852(b) of the Social Security Act (the Act), and with 42 C.F.R. § 422.110(a), which prohibits MA organizations from "deny[ing], limit[ing], or condition[ing] the coverage or … benefits … on the basis of any factor that is related to health status," such as medical condition or history, genetic information, and disability, among others.

AAHomecare supports CMS's proposal, and we recommend that CMS finalize these provisions. Additionally, we respectfully request that CMS take further steps to prevent discrimination against MA beneficiaries who rely on use of DME items to manage their health conditions. In comments submitted in response to CMS's Request for Information on Medicare Advantage Data (89 Fed. Reg. 5907, January 30, 2024) ("2024 RFI"), AAHomecare recommended that CMS require MA plans to report use of AI in care provision and decision-making. MA plans often utilize AI for claims and for prior authorization processes, but often incorrectly deny medically necessary services. As such, we again respectfully recommend that CMS require that MA plans publicly disclose use of AI in patient care.

III. Network Adequacy Requirements for Medicare Advantage.

Section 1852(d)(1)(A) of the Act authorizes MA organizations to "select the providers from which an enrollee may receive covered benefits," provided that the organizations make "such benefits available and accessible in the service area" in which the beneficiaries reside.[6] CMS uses the "county level" to determine the amount and type or providers and facilities with which an MA organization must contract to ensure adequate access for beneficiaries in an area. To ensure consistency in the application of CMS's network adequacy standards throughout the U.S., CMS proposes to define "county," under 42 C.F.R. § 422.116, to include "county equivalents" (as recognized by the U.S. Census Bureau), and amend the regulatory definition of "service area," under § 422.2, in conformity with this change.

AAHomecare recommends that CMS finalize these provisions. By clearly defining an MAO's designated area, CMS can help ensure that MA plans adhere to network adequacy standards by ensuring an adequate number of providers for the area. Additionally, we respectfully request that CMS ensure that MAOs adhere to network adequacy standards regarding DMEPOS access.

In previous comments to CMS, AAHomecare recommended that CMS require MA plans to establish clear network adequacy criteria by DMEPOS product category and by geographic area to ensure there is real patient choice. Some DMEPOS suppliers only provide respiratory items and services while others only provide complex rehab technology (CRT) items and services; therefore, there should be multiple DMEPOS suppliers providing the same product category in a geographic area. In the DMEPOS market, access issues can be due to a lack of competition for a particular product category in an area; when this occurs, it essentially removes any patient choice of supplier. For example, MA plans that limit the dispensing of CGMs to certain providers, such as pharmacies, ultimately limit—or outright remove—provider options for beneficiaries in the area.

We again respectfully request that CMS establish metrics to determine when network adequacy has been met for each product category in the DMEPOS space. CMS currently has established time and distance requirements for many other provider types (e.g., hospitals, skilled nursing facilities, physicians and home health agencies). Moreover, we respectfully ask that CMS require MAOs to submit data demonstrating compliance with network-adequacy standards for DMEPOS, such as number of in-network suppliers, by product category and by geography, and beneficiary satisfaction data. Further, there should be a clear channel within CMS that DMEPOS suppliers can use to escalate concerns about patient access issues. AAHomecare welcomes the opportunity to work with CMS to establish channels of communication for DMEPOS suppliers and develop metrics that would ensure access to care.

IV. Annual Health Equity Analysis of Utilization Management Policies and Procedures.

In the Contract Year 2024-2025 MA and Part D Final Rule (89 Fed. Reg. 30448, April 23, 2024) ("2025 Final Rule"), CMS enacted health equity regulations, under 42 C.F.R. § 422.137, which included requiring MAOs' utilization management committees to conduct annual health equity analyses on prior authorization (PA) use.[7] In comments for the 2025 Final Rule, stakeholders recommended that CMS require disaggregation by item and service to help the agency better identify specific items or services that may be disproportionately denied.[8] In response to these comments, CMS in the 2026 Proposed Rule

[6] 2026 Proposed Rule, at 99424.

[7] CMS, Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 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 (PACE), 89 Fed. Reg. 30448 (Apr. 23, 2024) ("2025 Final Rule").

[8] 2026 Proposed Rule, at 99343.

proposes to amend §§ 422.137(d)(6)(iii)(A) – (H) to revise the required metrics for the annual health equity analysis to require metrics reporting for each item or service, rather than aggregated amounts. If finalized, starting in 2025, analyses must include the following metrics for each covered item or service: percentage of PA requests that were approved, denied, approved after appeal, had extended review timeframes and were approved, had expedited PA requests and were approved, had expedited PA requests and were denied, and average and median time elapsed between PA request submission and determination by the MA plan (standard and expedited).[9]

AAHomecare appreciates CMS's consideration of comments requesting disaggregation by item and service, and we recommend that CMS finalize these proposed regulatory revisions. In addition, AAHomecare respectfully proposes further policies to improve MA plans' PA processes, with the concomitant need for MA plans to provide public data demonstrating that they are not inappropriately denying PA requests or patient access to care, including for DMEPOS items:

- MA plans should publish data on appeal processes for PA decisions for DMEPOS. Our members' experience is that many MA plans lack an objective or impartial and expeditious appeal process for negative PA determinations. We recommend that CMS require MA plans to establish a timely, objective PA appeal process for providers, suppliers, and enrollees to quickly appeal a negative PA determination. The deficiencies of current MA plan appeal processes are primarily lack of timeliness and a lack of impartiality and objectivity. For example, as discussed above, MA plans often deny beneficiaries NIV coverage based on application of the wrong Medicare LCD. Medicare has an NCD for NIVs, but no LCD for NIVs. MA plan coverage should therefore be based on the CMS published NIV NCD. Furthermore, when a physician prescribes NIV for a patient's lifetime, and the patient meets the Medicare NCD coverage criteria, MA plans often only approve temporary authorizations and later deny continued authorization requests with the same medical documentation originally submitted. Finally, MA plans should report the credentials and certifications of the individuals who participate in the "peer to peer" reviews that are conducted during the appeals processes.

- MA plans should be required to publicly disclose and report use of AI as part of the claims processing or PA processes, related to DMEPOS items. The algorithms and AI technology standards should be available for free to the public. As discussed above, MA plans often utilize AI for claims processing and PA processes, and often incorrectly deny medically necessary services.

- MA plans should publicly disclose and report all PA statistics for DME items, by product category. In addition, if an MA plan utilizes third party administrators (TPAs), or if an MA plan owns a DMEPOS supplier, those TPAs should be required to report the same metrics.

- Affirmative PA decisions should not be subject to reversal based on medical need: Based upon our members' experiences, many MA plans that issue affirmative PA decisions later reverse those decisions based upon medical need; this obviates the entire purpose of the PA process and, therefore, should not be allowed. An affirmative PA decision for a DME item should be conclusive with respect to the medical necessity for that item. Therefore, in the event of an audit, a claim that received an affirmative PA could only be audited for technical issues, such as proof of delivery. The audit should not include medical necessity because that is the objective of obtaining a PA decision. MA plans should be required to disclose data confirming that PA decisions do not get reversed based on medical need.

[9] 2026 Proposed Rule, at 99560.

V. Promoting Transparency for Pharmacies and Protecting Beneficiaries from Disruptions.

CMS is proposing to require Part D plan sponsors and first tier, downstream, or related entities, such as pharmacy benefit managers (PBMs), to notify network pharmacies, by October 1 of the year preceding a plan year, about the plans for which the pharmacies will be "in-network." Pharmacies must be given lists of these plans upon request. CMS further proposes to require contracts with pharmacies for participation in Part D networks, which allow plan sponsors to terminate without cause, to also permit the pharmacies to terminate the contracts without cause. According to CMS, these policies will "address concerns raised by pharmacies about their ability to provide accurate information to beneficiaries" and protect beneficiaries from any disruptions in care if network pharmacies cease to provide services before formally terminating their contracts.[10] AAHomecare appreciates CMS's efforts to protect beneficiaries from disruptions in care, due to changes in contracts between plan sponsors and pharmacies. We recommend that CMS finalize these proposals.

As discussed above, AAHomecare is aware that some MA plans now require beneficiaries to obtain their CGMs from in-network pharmacies only. Prohibiting DMEPOS suppliers from dispensing CGMs puts beneficiaries at risk of disrupted access to critical DME—here, CGMs to manage their diabetes. Moreover, policies that prevent beneficiaries from obtaining CGMs from certain types of providers—here, DMEPOS suppliers—and limit beneficiary access to only in-network pharmacies are inconsistent with statutory and regulatory requirements for the MA program. The MA statute prohibits MAOs from denying or limiting coverage "based on a health status-related factor" described in the Public Health Service Act ("PHS Act");[11] diabetes qualifies as a "health status-related factor" under the PHS Act.[12] The statute also prohibits MAOs from designing plans that "substantially discourage enrollment by certain MA eligible individuals within the organization."[13] These CGM access restrictions impose coverage limitations on the basis of diabetes, which surely discourages enrollment by this segment of the eligible population, since these patients could obtain CGMs through a supplier or a pharmacy with FFS Medicare. The statute further requires MAOs to cover all benefits available under FFS Medicare (Part A and Part B).[14] Under FFS Medicare, beneficiaries can obtain CGMs from any participating provider or supplier, but these MA policies only allow participating pharmacies to dispense CGMs; therefore, MA plans with limited dispensing policies do not provide benefits equivalent to FFS Medicare. Finally, MA policies that limit dispensing of CGMs to certain providers are inconsistent with the above-referenced § 422.112 network adequacy requirements. AAHomecare respectfully asks that CMS use its existing authorities to enforce, and to ensure MAO compliance with, all applicable requirements for the MA program. In particular, we urge CMS to clarify that an MA plan cannot maintain in effect any medical necessity or medical review policy that is more restrictive than the equivalent, applicable policy in the original (FFS) Medicare program.

Additionally, AAHomecare is aware that some MA plans shifted coverage for CGMs and related supplies from the DME medical benefit to the Part D pharmacy benefit; similar to dispensing limitations, coverage shifts disrupt care for beneficiaries enrolled in these plans. AAHomecare respectfully asks that CMS expand its proposed transparency efforts and beneficiary protections by requiring MA plans to disclose which of the benefits the plans cover under Part D are also covered under Part B. Medicare determined that CGMs are covered as DME under Part B, and MA plans are required to provide CGMs under Part B, but some MA plans are covering these devices and related supplies under Part D prescription drug plans.

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[10] 2026 Proposed Rule, at 99342.

[11] Social Security Act § 1852(b)(1) (codified at 42 U.S.C. § 1395w-22(b)(1)).

[12] *See* 42 U.S.C. § 300gg-4(a) (including "physical illness" among the general "medical condition[s]" that qualify, as well as any "[d]isability").

[13] Social Security Act § 1852(b)(1) (codified at 42 U.S.C. § 1395w-22(b)(1)).

[14] Social Security Act § 1852(a)(1)(A) (codified at 42 U.S.C. § 1395w-22(a)(1)(A)).

Therefore, we respectfully request that CMS issue rulemaking or guidance to clarify that CGMs, their related supplies, and other items covered by Medicare Part B within the DMEPOS benefit, are excluded from Part D. This is consistent with the Medicare Part D Manual definition of Part D covered drugs:

> "…medical supplies directly associated with delivering insulin to the body, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needlefree syringes, can satisfy the definition of a Part D drug. CMS defines those medical supplies to include syringes, needles, alcohol swabs, gauze, and those supplies directly associated with delivering insulin into the body."

Current Medicare policy allows certain medical supplies to be covered under the pharmacy benefit, but only when those items are not otherwise covered under Part B. Since CGMs and their supplies are clearly covered under the Medicare FFS DMEPOS benefit, MA plans must provide coverage for CGMs and related supplies under the Part B DMEPOS benefit. It is imperative that CMS enforce this requirement by requiring MA plans to report what benefits they are providing under the DME benefit versus under the pharmacy benefit.

VI. Formulary Inclusion and Placement of Generics and Biosimilars.

CMS is concerned about reports that "Part D sponsors and their PBMs engage in practices that favor, intentionally or unintentionally, more expensive brand drugs and reference products over generics, biosimilars, and other lower cost drugs in terms of formulary placement or non-placement."[15] CMS is seeking comments on "the prevalence of manufacturer rebates and the extent to which such rebates influence formulary decisions that reduce Part D beneficiaries' access to generics, biosimilars, and other lower cost drugs," and whether CMS should take further programmatic actions to prevent exclusions or disfavoring of generic, biosimilar, or lower-cost drugs.

AAHomecare appreciates CMS's efforts to address plan sponsor and PBM practices that exclude or disfavor lower-cost drugs; these practices cause disruptions in care and limit patient access to critical therapies. We recommend that CMS proceed with enacting protections in future rulemaking or guidance. Additionally, we respectfully request that CMS address MA plan policies to exclude certain providers from dispensing DMEPOS items. MA plan policies that limit dispensing of certain DMEPOS items, either due to favorability or rebates, lead to disruptions in care and limit access to essential therapies.

VII. Promoting Informed Choice—Expand Agent and Broker Requirements.

CMS is proposing to expand the list of requirements that agents and brokers must discuss with customers to include low-income supports (e.g., the Part D Low-Income Subsidy, Medicare Savings Programs, etc.), information on Medigap Federal guaranteed issue (GI) rights, implications of switching from MA to FFS Medicare, and requiring agents to answer questions before proceeding with enrollment, among others. AAHomecare supports these proposals and encourages CMS to finalize these policies. We agree that brokers should discuss Medigap coverage and ensure that beneficiaries are aware of potential restrictions on their ability to access Medigap in the future.

[15] *Id.* at 99470-72.

CONCLUSION

Thank you for the opportunity to provide comments. Please contact me at TomR@AAHomecare.org if you would like further information.

Sincerely,

Tom Ryan
President and CEO
American Association for Homecare