

January 27, 2025

Jeff Wu
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

RE: CMS-4208-P; Medicare and Medicaid Programs; 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.

Submitted electronically via regulations.gov.

Dear Acting Administrator Wu,

The National Rural Health Association (NRHA) is pleased to offer comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule for contract year (CY) 2026 policy and technical changes to the Medicare Advantage and Part D programs. We appreciate CMS' continued commitment to the needs of the more than 60 million Americans that reside in rural areas, and we look forward to our continued collaboration to improve health care access throughout rural America.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

II. Implementation of IRA Provisions for the Medicare Prescription Drug Benefit Program.

B. Appropriate Cost-Sharing for Covered Insulin Products under Medicare Part D (§§ 423.100 and 423.120).

Pursuant to the Inflation Reduction Act (IRA), CMS proposes to limit Part D cost-sharing for covered insulin products. NRHA supports CMS' proposed actions that ensure insulin is affordable. Diabetes is more prevalent in rural populations compared to urban populations.¹ Additionally, rural populations also have higher incidences of risk factors for developing diabetes, such as an aging population and higher rates of obesity.² As such, making insulin accessible for rural beneficiaries is paramount.

III. Strengthening Current Medicare Advantage, Medicare Prescription Drug Benefit, and Medicaid Program Policies.

¹ Rural Diabetes Prevention and Management Toolkit, RHIHUB, Sept. 2020, 8, <https://www.ruralhealthinfo.org/toolkits/diabetes.pdf>.

² *Id.*

A. Part D Coverage of Anti-Obesity Medications (AOMs) (§ 423.100) and Application to Medicaid Program.

Obesity is a highly prevalent and serious chronic disease affecting over 100 million Americans. Rural populations experience obesity at higher rates than urban populations and this disparity is growing. It is estimated that almost 39% of men and 47% of women living in rural areas have obesity compared to 32% and 38% of men and women in large metropolitan areas.³ Obesity is a risk factor for other adverse health outcomes such as heart disease, stroke, diabetes, certain types of cancer, and sleep apnea.⁴ As discussed above, rural residents also have a greater risk of obesity-related diseases, such as diabetes, than their urban counterparts.⁵ Treating obesity is a solution to mitigating some rural-urban disparities in chronic diseases and other adverse health outcomes.

Given these chronic disease disparities, NRHA is pleased to see that CMS proposes to allow Part D coverage of Anti-Obesity Medications (AOM). NRHA supports CMS' reinterpretation of "a covered Part D drug" as it pertains to AOM coverage for individuals with obesity and urge CMS to finalize this policy as proposed. CMS will be joining other major payers, including the Veterans Health Administration and state Medicaid programs in covering these medications, making treatment more accessible for the rural aging population.

Further, NRHA supports CMS' proposal to apply this policy change to Medicaid programs as well. About a quarter of rural residents are covered by Medicaid; however, just over a dozen state Medicaid programs allow for coverage of AOMs to treat obesity. Extension of this proposal will ensure equal access regardless of where a Medicaid enrollee lives.⁶

L. Ensuring Equitable Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost Sharing Limits (§§ 417.454 and 422.100).

NRHA applauds CMS for proposing to align MA cost-sharing with Traditional Medicare for behavioral health benefits, including intensive outpatient (IOP) services, mental health specialty services, opioid treatment program (OTP) services, and outpatient substance use disorder services, among others.

As CMS notes, MA beneficiaries generally face higher cost-sharing obligations when accessing behavioral health care compared to their Traditional Medicare counterparts. Considering that many MA beneficiaries enrolled in their MA plan because of perceived savings, closing this disparity between Part B and Part C beneficiaries is vital. NRHA urges CMS to finalize this policy as proposed and make behavioral health care more affordable for rural beneficiaries.

³ Craig M. Hales, et al., *Differences in Obesity Prevalence by Demographic Characteristics and Urbanization Level Among Adults in the United States, 2013-2016*, 319 JAMA 2419, 2422-55 (June 2018)

<https://jamanetwork.com/journals/jama/fullarticle/2685156>.

⁴ Demetrius Abshire & Cassidy Gutierrez, *Rural Obesity*, NATIONAL RURAL HEALTH ASSOCIATION, 1 (Oct. 2020)

https://www.ruralhealth.us/NRHA/media/Emerge_NRHA/Advocacy/Policy%20documents/2020-NRHA-Policy-Document-Rural-Obesity.pdf.

⁵ *Id.*

⁶ Elizabeth Williams, Robin Rudowitz, & Clea Bell, *Medicaid Coverage of and Spending on GLP-1s*, KFF (Nov. 4, 2024), <https://ccf.georgetown.edu/2023/08/17/medicaids-coverage-role-in-small-towns-and-rural-areas/>; <https://www.kff.org/medicaid/issue-brief/medicaid-coverage-of-and-spending-on-glp-1s/>.

O. Promoting Informed Choice – Expand Agent and Broker Requirements Regarding Medicare Savings Programs, Extra Help, and Medigap (§§ 422.2274 and 423.2274).

2. Medicare Supplemental Insurance (Medigap).

CMS proposes to require that MA agents and brokers discuss eligibility for the low-income subsidy (LIS), the Medicare Savings Program (MSP), and Medigap prior to completing enrollment with a potential beneficiary. NRHA supports this proposal and asks CMS to finalize as proposed.

NRHA is particularly supportive of the inclusion of Medigap in enrollment discussions. NRHA members have shared many stories of beneficiaries who were unknowingly enrolled in an MA plan or enrolled without understanding the implications to their coverage should they choose to transition back to Traditional Medicare. While it is possible for beneficiaries to change plans during open enrollment, there are barriers to doing so, such as cost.

One typical reason that beneficiaries choose MA plans is because out-of-pocket costs are lower without having to buy a supplement, or Medigap, plan. MA plans typically cover premiums, but Traditional Medicare does not unless the beneficiary purchases a Medigap plan. Beneficiaries that want to switch from an MA plan to Traditional Medicare must be underwritten for a Medigap policy and beneficiaries may be denied a policy if they do not meet medical underwriting requirements. NRHA members have significant concerns around beneficiary understanding around this policy. As such, NRHA believes that CMS' proposal is an important first step to protecting beneficiaries from losing guaranteed issue rights to a Medigap plan.

U. Enhancing Rules on Internal Coverage Criteria.

1. Using Internal Coverage Criteria to Interpret or Supplement General Provisions.

CMS is clarifying that plans may only use internal coverage criteria when national coverage decisions (NCD) and local coverage decisions (LCD) lack specificity or clarity. In such instances, plan-specific internal coverage criteria may be used to supplement or interpret the plain language of coverage provisions. NRHA supports this clarification as it will strengthen protections against unnecessary delays and denials of care.

2. Definition of Internal Coverage Criteria.

Related to the proposal above, CMS proposes to define “internal coverage criteria.” *CMS proposes to define this term as “any policies, measures, tools, or guidelines, whether developed by an MA organization or a third party, that are not expressly stated in applicable Medicare 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 [...]. This includes any coverage policies that restrict access to or payment for medically necessary [...] items or services[.]”* NRHA supports this comprehensive definition.

Further, we strongly support CMS' proposed guardrail to prohibit plan use of internal coverage criteria when such criteria have no clinical benefit or are used to automatically deny coverage of benefits without an individual medical necessity determination. Put together, these two clarifications

in § 422.101 could curb inappropriate use of internal coverage criteria to prevent rural beneficiary access to needed care.

V. Clarifying MA Organization Determinations To Enhance Enrollee Protections in Inpatient Settings.

Utilization management processes, such as prior authorization and other reviews by MA plans, are affecting both rural and urban providers. However, under resourced rural providers do not have the staff needed to handle arduous MA plans' prior authorization and review processes. Consequently, NRHA members experience high administrative burden, are paid less than traditional Medicare, and have little recourse to address MA plan abuses. NRHA hears the majority of complaints around approval for inpatient admissions. MA plans stall when responding to a prior authorization request for an inpatient stay, and in many other cases plans outright deny inpatient admissions or downgrade to outpatient or observation status after the hospital has already admitted the beneficiary.

1. Clarifying When a Determination Results in No Further Financial Liability for the Enrollee (§ 422.562).

NRHA urges CMS to finalize its proposal to clarify when “no further financial liability” for the MA beneficiary applies in regard to their appeal rights. When adverse coverage decisions are made, beneficiaries generally have a right to appeal such a decision. However, when a payment decision is made by a plan (i.e., whether the plan will pay a provider or deny payment), generally the beneficiary no longer has a right to appeal the decision. MA plans have found workarounds to classifying coverage decisions as payment decisions and thus limiting both an enrollee's right to appeal and payments to providers. This change will clarify that the limitation of an enrollee's appeal rights only applies if a request for payment from a provider is submitted to the MA plan.

NRHA urges CMS to finalize this clarification as proposed in order to ensure enrollees' rights to appeal adverse coverage decisions are safeguarded and cleanly separate the administrative appeals process and payment decision process.

2. Clarifying the Definition of an Organization Determination To Enhance Enrollee Protections in Inpatient Settings (§§ 422.138 and 422.566).

NRHA regularly hears from members about situations where a hospital admits a beneficiary, notifies the MA plan of the admission, and while the beneficiary is still receiving inpatient care the MA plan makes an adverse coverage decision (“concurrent review”). Ultimately, when the hospital requests payment, the plan denies payment because of their concurrent review decision. It is then up to the hospital to work with the MA plan to reverse its coverage and payment decisions and oftentimes the beneficiary is not aware that this is happening. This can lead to uncertainty around beneficiaries' cost-sharing obligation or surprise bills.

NRHA supports CMS' proposal to strengthen language around coverage decision made during concurrent review. This change would require that beneficiaries are notified of decisions made during their receipt of services, as well as pre- or post-service, and thus affords beneficiaries their rights to timely notice and appeal. NRHA hopes that this change will help combat some issues around

improper denials of inpatient care, which is one of NRHA members' most pressing concerns with MA plans.

Another area that CMS proposes to address is retrospective reviews. Again, NRHA regularly hears from members about MA plans' retrospective review of inpatient admissions in which a beneficiary receives inpatient care and is discharged. Then the MA plan notifies the hospital that it is denying payment for the stay and orders the hospital to bill the inpatient care as an outpatient claim. Again, the beneficiary is often not given notice of this decision and thus loses their appeal rights. NRHA supports CMS' proposal to ensure that beneficiaries receive timely notice and appeal rights when retrospective reviews are made by plans.

Last, CMS proposes to strengthen its regulation finalized in April 2023 prohibiting plans from denying coverage for services that the plan previously approved through prior authorization. CMS now proposes to add decisions made during concurrent review to this regulation. Decisions on coverage made by plans while the provider is furnishing services are relied upon in the same way as prior authorization decisions and should not be reexamined and later denied by plans.

3. Strengthening Requirements Related to Notice to Providers (§§ 422.568, 422.572, and 422.631).

NRHA supports CMS' proposal to require that MA plans provide notice of organization decisions to both MA beneficiaries and their providers. NRHA concurs with CMS' reasoning that if a provider submitted a request on behalf of a beneficiary the provider has an interest in receiving notice of the plan's determination, in addition to notice sent to the beneficiary.

4. Modifying Reopening Rules Related to Decisions on an Approved Hospital Inpatient Admission (§§ 422.138 and 422.616).

CMS notes that it is aware of MA plans reopening and revising or otherwise rescinding a prior approval for an inpatient hospital admission based on a medical necessity determination during the beneficiary's receipt of the previously authorized services or during the adjudication of the inpatient claim for payment. Again, NRHA can corroborate that our members frequently deal with this exact situation.

In its CY 2024 rule, CMS finalized a regulation prohibiting an MA organization from approving the furnishing of a covered item or service through a prior authorization coverage or payment and later denying coverage due to lack of medical necessity. However, CMS included an exception for "good cause" or fraud. One foundation for good cause is "there is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion." NRHA raised concerns around the exception for "good cause" and the possibility of MA plans abusing this exception.⁷ We appreciate CMS' willingness to revisit this policy decision to protect rural beneficiaries.

NRHA's concern was well-founded as CMS is now reinforcing guardrails against this practice, specifically for inpatient admissions. NRHA agrees with CMS' reasoning that physicians can only

⁷ See National Rural Health Association, Comment on Contract Year 2024 Medicare Advantage Policy and Technical Changes proposed rule (Feb. 13, 2023), 7 <https://www.ruralhealth.us/getmedia/ee25e8f8-38f2-4705-87b3-5ec44ffce154/CY2024-MA-Policy-and-Technical-Changes-comment-2-13-23.pdf>.

admit beneficiaries based on clinical information known at that time as well as the documented medical record at the time of admission. As such, any subsequent information obtained by MA plans could not logically serve as “new and material evidence” that would “result in a different conclusion” under the “good cause” exception.

NRHA strongly supports CMS’ new language at proposed § 422.616(e) that strictly prohibits using any additional clinical information obtained after the MA plans’ initial approval of an inpatient admission in order to establish “good cause” for reopening the determination of approval.

NRHA thanks CMS for the proposed clarifications and safeguards in Section V and urges the agency to continue strengthening coverage and payment protections for MA beneficiaries and rural providers. While NRHA is broadly supportive of the reforms proposed in the sections above, we note that these changes, if finalized, only have the ability to improve beneficiary access to care and provider payment if they are rigorously enforced by CMS. We urge the agency to increase its oversight of MA plan practices as they relate to delaying and denying care and payment. **We urge CMS to hold plans accountable for unnecessarily denying coverage or payment for inpatient services** when all documentation and medical decision making by providers points to the need for services, especially inpatient admissions. NRHA appreciates the strides made towards this goal in the proposals above but cautions CMS that NRHA members regularly experience MA plans finding loopholes or in some cases blatantly disregarding regulations. Since CMS finalized the CY 2024 rule, NRHA members have expressed that plans are not complying with the prior authorization rules. Rural hospitals are spending more and more time fighting adverse coverage and payment decisions, especially those made during concurrent and retrospective reviews. Many times rural hospitals cannot pursue recourse and are forced to accept lower payment for services already furnished.

Other MA issues not addressed in the proposed rule:

Timeliness and Denials of Payment.

MA plans delay payment or make the process of getting paid the correct amount so time consuming and burdensome that rural providers do not have adequate staff, time, or resources to address every payment issue or to pursue timely and accurate payment. In extreme circumstances, NRHA members have noted up to \$800,000 in delayed or denied payments. For rural hospitals that with thin or negative margins delayed payments are a critical cash flow issue. **Half of rural hospitals operate on negative margins, and they cannot absorb this level of untimely payments.**⁸ Furthermore, administrators are frustrated with untimely payments because it is difficult to operate and plan without predictable payments from a growing number of their patients.

As the ultimate payer of MA plans, **CMS must use its authority to ensure that MA plans are properly using federal funds when paying rural providers.** MA regulations state that contracts between CMS and MA plans must include a provision mandating that the plan will pay 95% of “clean

⁸ Michael Topchik, et al., *Unrelenting Pressure Pushes Rural Safety Net Crisis into Uncharted Territory*, Chartis (2024), 2, https://www.chartis.com/sites/default/files/documents/chartis_rural_study_pressure_pushes_rural_safety_net_crisis_into_uncharted_territory_feb_15_2024_fnl.pdf.

claims” within 30 days of receipt.⁹ MA regulations further provide the definition of a clean claim.¹⁰ Given that CMS identified other loopholes that MA plans use to delay and deny care and payment, the agency must enforce the clean claims provision, investigate whether plans are meeting the 95% threshold, and if they are determining correctly whether claims are clean. MA plans must not be permitted to delay and deny payments that are properly prepared with substantiating documentation by alleging that the claim is not “clean” and therefore cannot be paid within 30 days. **Traditional Medicare must pay providers within 30 days and MA plans must be held to the same standard.** CMS should also mandate reporting by MA plans on the rate of timely payments to providers and make this information publicly available for providers.

Even after payments are made to providers, plans will perform post-audits. NRHA members have experienced audits by MA plans that probe back as far as 4 years in an effort to recoup payments. MA plans should not have unmitigated authority to perform audits that go back years. Providers are subject to billing deadlines and similarly, **MA plans should be subject to look back period restrictions for auditing payments.**

NRHA thanks CMS for the opportunity to submit comments on this proposed rule. We look forward to our continued work together. If you have any questions or would like to discuss our response further, please contact NRHA’s Government Affairs and Policy Director, Alexa McKinley Abel at amckinley@ruralhealth.us.

Sincerely,



Alan Morgan
Chief Executive Officer
National Rural Health Association

⁹ § 422.520(a)(1).

¹⁰ § 422.500(b).