February 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

RE: CMS-4201-P; Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

Submitted electronically via regulations.gov.

Dear Administrator Brooks-LaSure,

The National Rural Health Association (NRHA) is pleased to offer comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule for calendar year (CY) 2024 policy and technical changes to the Medicare Advantage program. 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.

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Health Equity in Medicare Advantage (MA) (§§ 422.111, 422.112, and 422.152)

2. Ensuring Equitable Access to Medicare Advantage (MA) Services (§ 422.112)
NRHA supports the revised language under 42 C.F.R. § 422.112(a)(8) ensuring that culturally competent services are provided to all enrollees. NRHA appreciates the inclusion of people living in rural areas, groups with limited English proficiency or reading skills, and those affected by persistent poverty. Rural beneficiaries require services that consider their unique geographic and socioeconomic challenges.

3. Medicare Advantage (MA) Provider Directories (§ 422.111)
NRHA further supports including a new data element in MA provider directories for providers who offer medications for opioid use disorder (MOUD). Knowing where to receive behavioral health services is one major barrier to seeking care for rural adults.⁠¹ Requiring MA organizations (MAOs) to indicate providers that can prescribe MOUD is one step towards helping rural adults know where to receive treatment for OUD. This is especially important now as substance use disorders (SUD), including opioid use, have grown during the COVID-19 pandemic and startlingly low numbers of those indicating that they suffer from SUD sought treatment in 2021.²

B. Behavioral Health in Medicare Advantage (MA) (§§ 422.112, 422.113, and 422.116)

2. Behavioral Health Specialties in Medicare Advantage (MA) Networks (§§ 422.112 and 422.116)
NRHA applauds CMS’ addition of clinical psychologists, clinical social workers, and MOUD prescribers to the provider specialty types. Requiring that MAOs contract with at least one of each of these providers in each network will expand MA beneficiaries’ access to behavioral health services. In general, rural communities often rely on behavioral health professionals other than physicians or doctorate-level individuals. Specifically, clinical psychologists and clinical social workers are especially important to rural beneficiaries because rural communities often rely upon masters’-level practitioners to meet behavioral health workforce needs.

Nonetheless, NRHA is still concerned with MA beneficiary access to MOUD, in particular methadone. Even though § 422.116(a)(2) states that MAOs must contract with at least one of each specialty provider type, and that each provider must be within the maximum time and distance requirements of at least one plan beneficiary, this may not be enough for rural beneficiaries seeking MOUD prescribers.

CMS is proposing that MOUD prescribers include opioid treatment programs (OTPs) and/or practitioners with a waiver under section 303(g)(2) of the Controlled Substances Act (CSA). OTPs are the only providers that can dispense methadone for OUD, so even if an MAO contracted with a waivered practitioner in one plan network, that plan would not have access to methadone via an OTP. Given recent efforts by the federal government to expand access to OTPs and methadone,³ CMS should consider separating waivered practitioners and OTPs as two different specialty providers for network adequacy purposes.

Additionally, the number of OTPs in rural areas is troubling. According to NRHA’s internal analysis, only about 220 of 1,900 Substance Abuse and Mental Health Services Administration (SAMHSA)-certified OTPs are located in rural zip codes. This lack of rural OTPs becomes even more acute depending upon the state. For example, out of 168 OTPs in California, 2 are available in rural areas

---

³ The Substance Abuse and Mental Health Services Administration is proposing to update its regulations on OTPs to allow for take home doses of methadone, telehealth for prescribing, and other flexibilities. Also, the calendar year 2023 Medicare Physician Fee Schedule final rule allowed coverage of OTP services at mobile medication units.
and only 1 out of 17 OTPs in Minnesota is rural. Some MAOs may be unable to contract with even one OTP in its service area due to provider availability in certain states. This would result in rural beneficiaries in a plan being unable to access methadone.

Compounding the lack of rural OTPs is the use of prior authorization. Since Medicare began covering OTP services in 2018, providers have expressed that prior authorization practices by MAOs have made it difficult for beneficiaries to get methadone for OUD. For a beneficiary struggling with OUD, the timeliness of treatment matters, especially if they are in withdrawal or are likely to use opioids again. About 85% of MA plans use prior authorization for OTPs, meaning that majority of beneficiaries must take an additional step before receiving OTP services. CMS must address this unnecessary barrier to care to ensure rural MA beneficiaries can access lifesaving treatment.

NRHA also recommends changing the language to reflect provisions of the Consolidated Appropriations Act of 2023 (CAA, 2023) for waived providers under § 303(g) of the Controlled Substances Act (CSA). The CAA, 2023 removed the “X-waiver”, or the requirement at § 303(g) that providers must submit a Notice of Intent to prescribe schedule III, IV, and V drugs, which includes buprenorphine, for treating OUD. This likely requires only a language change to clarify that the other type of specialty provider subject to network adequacy standards is a practitioner that dispenses and prescribes schedule III, IV, and V drugs for OUD treatment. CMS should revise the language at §422.116(b)(1)(xxx) to:

“(xxx) Prescribers of Medication for Opioid Use Disorder (MOUD) (including MOUD-Waivered Providers and/or Opioid Treatment Programs (OTPs)). For purposes of this regulation, MOUD-Waivered Providers means providers who are waived by the Substance Abuse and Mental Health Services Administration and the Drug Enforcement Agency to administer, dispense, or prescribe narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment for opioid use disorder in accordance with section 303(g)(2) of the Controlled Substances Act, and OTPs means OTPs as defined in section 1861(jjj)(2) of the Act.”

NRHA supports the proposal to add a ten-percentage point increase to the number of beneficiaries that reside within published time and distance standards when a specialty provider provides additional telehealth benefits. Telehealth is a crucial tool for rural beneficiaries that can help ease the burdens associated with transportation challenges. Telehealth is a key part of any rural health care delivery system and should be incentivized in MA plans where appropriate.

3. Behavioral Health Services in Medicare Advantage (MA) (§§ 422.112 and 422.113)
NRHA is broadly supportive of proposals that strengthen rural beneficiaries’ access to behavioral health services. Adding behavioral health conditions to the definition of emergency medical conditions is a positive step towards creating parity between behavioral and physical health in MA plans and also allows beneficiaries to receive emergency mental health care without regard for prior

---

5 Id.
6 Id.
NRHA asks that CMS clarify in the final rule that substance use-related emergencies, like drug or alcohol poisoning or opioid overdose, are included in the definition of mental health emergencies at §422.113(b)(1)(i). An overdose falls within the proposed definition at §422.113 as it is a condition that “one could reasonably be expected to cause serious injury (or death) to oneself if one’s behavioral health condition results in a suicide plan, attempt, other suicidal behavior, or other forms of serious self-harm.”


Another proposal that creates parity for primary care and behavioral health is at §422.112(a)(6) which would assign the same minimum standards for appointment wait times for both types of services. NRHA urges CMS to consider a shorter timeframe – 15 days – for routine and preventive care.

MA regulations provide a definition for emergency or urgently needed services in §422.113(b)(1). When an MAO is ensuring that a beneficiary finds urgently needed primary or behavioral health services, this is the standard in the regulations against which the MAO can determine if the services are urgently needed. NRHA is concerned about the wait time for “services that are not emergency or urgently needed, but the enrollee requires medical attention.” This type of service is not defined within the regulations, and we foresee situations where a beneficiary does need medical attention, but it is determined that the service would fall under routine or preventive instead. CMS should provide definitions or examples for services in which an enrollee requires medical attention in §422.113(a)(6).

C. Medicare Advantage (MA) Network Adequacy: Access to Services (§422.112)

At proposed §411.112(a)(1)(iii) CMS is proposing to codify the existing requirement from the Medicare Managed Care Manual (MMCM), Chapter 4, that MAOs must arrange for medically necessary out-of-network services at in-network cost sharing prices if medically necessary covered benefits are not available within the plan network. Overall, this codification is a positive for beneficiaries as they should not pay more because the plan network is inadequate.

Nevertheless, this change may still leave room for MAOs to arrange for care that may not be in the beneficiary's best interest. The proposed text specifies that the plan arranges for the medically necessary service. For example, the plan may send a beneficiary to a provider that offers the medically necessary service regardless of specific quality outcomes or the time and distance to the beneficiary's home or family. Beneficiaries should have options regarding where they receive the out-of-network care. Ensuring choice is particularly important for rural beneficiaries who, on average, travel longer and further to reach care. An MAO may not be cognizant of transportation challenges and the beneficiary's best interest when assigning the beneficiary to a SNF or other needed benefit.

CMS should include language in proposed §422.112(a)(1)(iii) that the MAO must:
“[a]rrange for any medically necessary covered benefit outside of the plan provider network, considering enrollee preferences, but at in-network cost sharing when an in-network provider or benefit is unavailable or inadequate to meet an enrollee’s medical needs.”

Adding enrollee preference to the regulatory text will specify that MAOs must arrange for out-of-network services at a setting and location that best fits the enrollee’s needs to reduce burdens on rural enrollees and their families or caretakers.

D. Enrollee Notification Requirements for Medicare Advantage (MA) Provider Contract Terminations (§§ 422.111 and 422.2267)

NRHA supports the proposed revised enrollee notification requirements at § 422.111. Again, equivalent provider termination notice requirements for behavioral health and primary care creates parity between the two and emphasizes the importance of behavioral health. NRHA also applauds the longer proposed timeline for notification for behavioral health and primary care – at least 45 days before the effective termination date – compared to the current 30 days. Last, NRHA supports giving written notice for behavioral health, primary care, and specialty care notifications as is typically the most effective way to reach rural beneficiaries, as opposed to using technology.

The proposed content requirements for enrollee notifications at § 422.2267(e)(12) give needed guidance that will aid in continuity of care. While comprehensive enrollee notification does not solve all continuity of care issues associated with provider termination, it does encourage enrollees to continue to seek care when their provider leaves the network. For example, the proposal to include contact information for in-network providers should encourage enrollees to contact a new provider rather than forgo care.


NRHA members have consistently expressed serious concerns over the prior authorization practices of MAOs. Additionally, the Department of Health and Human Services Office of the Inspector General released a report in April 2022 outlining that some MAOs improperly deny medically necessary care which results in beneficiaries losing access to needed items and services. This report aligns with what NRHA has heard from our members. NRHA supports CMS’ proposals that strengthen prior authorization protections for beneficiaries.

2. Coverage Criteria for Basic Benefits

---

8 Please see our response to the CMS August 2022 request for information on Medicare Advantage: https://www.ruralhealth.us/NRHA/media/Emerge_NRHA/2022-08-31-Medicare-Advantage-RFI.pdf.
10 Please see our response to the CMS August 2022 request for information on Medicare Advantage: https://www.ruralhealth.us/NRHA/media/Emerge_NRHA/2022-08-31-Medicare-Advantage-RFI.pdf.
MAOs are required to make medical necessity determinations for prior authorization requests based on criteria that is no more restrictive than national and local coverage policies for Traditional Medicare. As discussed, MAOs often deny an item or service that is medically necessary based upon more restrictive guidelines. To curb this, NRHA supports the clarifying language in § 422.101(b)(2) stating that MAOs must comply with general coverage and benefit conditions under Traditional Medicare.

We are also pleased to see the more stringent requirements for MAOs to develop internal coverage criteria based upon widely used treatment guidelines or clinical literature in § 422.101(b)(6). When Traditional Medicare does not provide coverage criteria for certain items and services, MAOs should follow evidence-based guidelines when developing their own coverage criteria. The proposed regulation requires that MAOs make such evidence publicly available, and NRHA asks that CMS also require MAOs to make their internal coverage criteria public.

NRHA members have raised concerns about MAO prior authorization practices for SNF and swing bed care. Traditional Medicare beneficiaries are entitled to 100 days of SNF care covered by Medicare as long as the criteria for SNF admission is met. Unfortunately, MAOs do not always authorize SNF admissions for the length of time that the beneficiary needs. Further, MAOs will use their own criteria to determine the medical necessity and thus length of time that a beneficiary supposedly needs skilled nursing care. NRHA has learned that MAOs may authorize up to a certain number of days in a SNF and then require the provider to submit another prior authorization request to extend the stay. This creates excessive administrative burden for understaffed rural SNFs and continuity of care challenges for beneficiaries.

NRHA also suggests adding explicit language on coverage of different provider types or settings for a service. In the preamble to the proposed rule CMS states that § 422.101(b) and (c) read together would not allow an MAO to redirect a patient to another setting for care when a provider orders a particular setting. For example, a provider may order post-acute care at a SNF and then MAO may redirect the beneficiary to receive home health services. CMS believes that the proposed regulatory text in the above subsections would not allow this practice unless the beneficiary does not meet covered criteria. However, NRHA believes that this practice should be explicitly prohibited in the regulatory text. Additionally, language should protect beneficiaries from being sent to a SNF when equivalent post-acute services can be provided at a closer, in-network hospital through swing bed services, or vice versa.

Members are also concerned about prior authorization by MAOs for inpatient admissions. We have heard examples of MAOs preliminarily authorizing an inpatient admission and after the patient is discharged retrospectively stating that the patient did not meet the criteria for an inpatient admission and thus the MAO will not pay. Traditional Medicare uses the “two midnights” rule for inpatient admissions and MAOs should only make inpatient prior authorization decisions based on this criterion as well.

NRHA is hopeful that the proposed language in §§ 422.101(b)(2) and 422.101(c) address these issues by reiterating that the statutes and regulations applicable to Traditional Medicare are also applicable to Medicare Advantage. Specifically listing that this standard applies to inpatient admissions and
coverage requirements for SNF care in 422.101(b)(2) is crucial because these two areas have been of utmost concern to NRHA members.

However, NRHA members have provided examples of loopholes that MAOs use to avoid following Traditional Medicare. One member noted that MAOs include provisions in their contracts with providers that the MAO will use particular criteria for determining medical necessity like internal policies on how a beneficiary would meet acute status and therefore be admitted to inpatient care. However, the policies used are not based upon Traditional Medicare’s two midnights rule. The MAO then puts the provider in a “take it or leave it” situation regarding the contract – either the provider agrees to all provisions, or they cannot contract with the MA plan and provide in-network care for the patients they serve in that MAO. Rural providers do not have the leverage or resources to negotiate with the MAO to remove provisions that restrict beneficiaries’ access to medically necessary services. CMS should monitor whether MAOs use extra-regulatory actions such as contracting around MA program requirements.

3. Appropriate Use of Prior Authorization
NRHA appreciates the new proposed § 422.138(a) which outlines that prior authorization can only be used to confirm the presence of a diagnosis, to ensure that basic benefits are medically necessary, or to ensure that supplemental benefits are clinically appropriate. This new language reflects longstanding guidance from the MMCM and NRHA believes this creates a stronger protection for beneficiaries by being codifying in the regulatory text.

NRHA also supports the new language stating that MAOs cannot retroactively deny coverage or payment for a previously approved request. NRHA members have, as noted above, explained situations in which an MAO that previously approved a prior authorization request as medically necessary later denies coverage on the basis that the item or service was not medically necessary. Members have voiced that this is especially an issue for inpatient admissions. NRHA supports the proposed text as § 422.138(c) stating that MAOs may not revoke prior authorization on the basis that it is not medically necessary. However, the reopening exception for good cause or fraud in that subsection may potentially leave room for MAOs to reopen prior authorization approvals under the guise of those bases in bad faith to revoke an item or service that was medically necessary. CMS should be prepared for this in the event that it happens and consider how to ensure the reopening process is not abused.

4. Continuity of Care
NRHA supports proposed provisions that strengthen continuity of care protections for beneficiaries. Practices by some MAOs cause disruptions in care for rural beneficiaries, which can result in poor health outcomes and significant administrative burden for providers, as discussed above.

Proposed § 422.112(b)(8)(i) would require that MAOs approve a prior authorization request for the duration of the approved course of treatment. This, in conjunction with proposed § 422.138, discussed above, should in theory protect beneficiaries from losing access to necessary items and services as well as reduce administrative burden for understaffed rural providers. When MAOs do not authorize a covered service for the entire course of treatment, and require providers to submit several repetitive requests, this creates extra work for already overworked rural providers. The same is true when prior authorization approvals are retroactively denied, and providers must work to
appeal the decision. This also creates uncertainty and disruptions in needed care for beneficiaries that may lead to poor health outcomes in some situations. NRHA supports the inclusion of continuity of care provisions insofar as they protect beneficiaries from inappropriate denials and simplify administrative burdens for providers.

Additionally, proposed § 422.112(b)(8) includes protections for beneficiaries that change MA plans. If finalized, MAOs would be required to provide a 90-day period for any previously approved courses of treatment, even if the treatment was with a provider that is out-of-network in the new plan. During the 90 days the MAO cannot require additional prior authorization for the current course of treatment for the new beneficiary. NRHA supports this proposal as it will ensure beneficiaries do not lose access to needed services because they switch plans. This proposal, alongside proposals in CMS’ Advancing Interoperability and Improving Prior Authorization Processes, should easily be implemented. Active courses of treatment should be recorded in a beneficiary’s medical record and these records would be communicated from payer-to-payer in the proposed application program interfaces (API) from the Advancing Interoperability proposed rule. Additionally, the payer-to-payer API in the Advancing Operability proposed rule would include information on prior authorizations, including active requests. NRHA supports this proposal as it does not put the onus on providers to communicate the patient’s current treatments from the old plan to the new plan.

6. Additional Areas for Consideration and Comment
NRHA members have expressed the same concerns about termination of post-acute care that are referenced in this section. Members noted that MAOs will authorize post-acute care at a SNF and then terminate the service even though the beneficiary is not healthy enough to return home. This practice not only disrupts continuity of care but can create a dangerous situation in which a beneficiary is sent home and cannot care for themselves. In rural areas where older adults are more isolated from family members or a support system, this is even more unsafe.

While NRHA supports the changes regarding medical necessity at § 422.101(b)(2) and (c)(1)(i), the revision may not be strong enough to protect against early termination of post-acute care. For example, when services can be provided in more than one setting, CMS states that the new language in § 422.101(c)(1)(i) only allows MAOs to deny coverage of services in a setting because the setting fails to meet the criteria outlined in that section. NRHA believes that this only mitigates against early post-acute care termination in an indirect way. Subsection (c) should include explicit language on how MAOs can approve or deny coverage based on the setting that care is provided in with reference to improper early termination.

NRHA supports requiring a clinical rationale for early termination of post-acute care. The current language in § 422.624 does not require an explanation for termination by an MAO. For transparency purposes, and to aid with the fast-track appeals process under § 422.626, a justification based upon clinical standards is necessary.

H. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional With Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to

11 87 FR 76238.
Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629)

NRHA generally supports a physician or other health professional with expertise in the field of medicine that is appropriate for the item or service being requested to review the prior authorization request before an adverse decision is made. Narrowing the review requirement at proposed § 422.566(d) from a professional with sufficient expertise to a professional with expertise that is relevant to the specific item or service should reduce the number of prior authorization denials.

The health professional review standard is not new; however, NRHA anticipates that the MAO arranging a reviewing physician with the relevant specialty may make prior authorization review take longer than under the current standard. CMS notes in the preamble that this slight change to the regulatory text would not result in additional burdens on the MAO. Nonetheless, NRHA encourages CMS to ensure that this change does not result in MAOs extending the time needed to review prior authorization requests.

P. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423)

Misleading marketing and advertising by MAOs have garnered major concerns from NRHA members. Certain direct outreach to MA beneficiaries or traditional Medicare beneficiaries, along with MAO advertising practices, often influence older adults to explore, and potentially enroll in, other coverage options that do not align with their best interests.

The Senate Finance Committee released a report based on responses from 14 states about MAO marketing that found that CMS received double the number of complaints regarding marketing from beneficiaries in 2021 compared to 2020. Mail and TV advertisements, robocalls, and telemarketers were among the top sources of complaints. These advertisements included false or misleading content such as mail that appeared to be from CMS or otherwise from the federal government because it used Medicare branding. Advertisements also included misleading information about increases to enrollee’s Social Security checks or other benefits that were not available in an enrollee’s area. These examples of marketing and advertising are troubling because enrollees may switch to plans that do not include their current providers or do not best meet their health needs.

NRHA applauds CMS for addressing the abovementioned practices by MAOs and third-party marketing organizations (TPMOs) in this proposed rule. CMS must take actions to protect rural older Americans with less health, technology, and media literacy from misleading information. When MAOs contact enrollees or potential enrollees, or include deceptive information in marketing, older adults will be encouraged to contact the plan and likely be subject to additional marketing. This tactic leads to traditional Medicare beneficiaries, or enrollees in an MAO that currently fits their needs, to be enticed to switch plans based on the advertised benefits. NRHA finds this problematic because enrollees in a new plan may not understand how their coverage has changed, including that their

---

providers may now be out-of-network. This practice is not only misleading but dangerous for enrollees that do not understand the health implications of new coverage.

NRHA supports the proposed § 422.2262(a)(1)(xix) that prohibits MAOs using the Medicare name, CMS logo, and any products and information from the federal government in a misleading way. Older adults with lower media literacy may believe that they are being contacted by CMS or HHS rather than an MAO. NRHA also supports § 422.2262(a)(1)(ii) that prohibits use of superlatives unless supported by documentation or data published in the current or prior contract year.

Proposed § 422.2263(b)(8) addresses MAOs advertising benefits like dental coverage or Social Security rebates as available nationwide when the benefits are only available in select states. NRHA supports finalizing this subsection as proposed. Further, NRHA supports § 422.2263(b)(9) and (10) as they prohibit MAOs from providing deceptive information in marketing materials.

NRHA also supports § 422.2264(b)(2) requiring that MAOs must give all beneficiaries that the MAO contacts for plan business notice of their ability to opt out of future calls about plan business. NRHA particularly supports the requirement that this notice be provided annually and in writing. Mail is often the most effective way to reach rural enrollees that do not use online communications as frequently.

As referenced throughout this comment, the main concern surrounding misleading marketing and advertising for NRHA and our members is enrollees not understanding the differences between coverage options. This is a problem when an enrollee is enticed to choose a new plan through marketing tactics and does not understand the key differences between their new plan and their old plan, especially when the new plan provides less comprehensive coverage. In proposed § 422.2267(e)(4)(viii), NRHA supports the addition of "effect on current coverage" in the pre-enrollment checklist that plans must provide to a prospective enrollee along with the enrollment form. NRHA further supports the proposed requirement that during enrollments via phone, the MAO representative must walk through the pre-enrollment checklist with the prospective enrollee prior to enrollment.

Thank you for the chance to offer comments on this proposed rule and for your consideration of our comments. We look forward to continuing our work together to ensure our mutual goal of improving quality and access to care for rural residents. If you would like additional information, please contact Alexa McKinley at amckinley@ruralhealth.us.

Sincerely,

Alan Morgan
Chief Executive Officer
National Rural Health Association