AMERICAN ACADEMY OF FAMILY PHYSICIANS

February 13, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 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**

Dear Secretary Becerra and Administrator Brooks-LaSure:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 127,600 family physicians and medical students across the country, I write in response to the proposed rule regarding changes to Medicare Advantage (MA) and the Medicare Prescription Drug Benefit Program for Contract Year 2024 as published in the Federal Register on December 27, 2022. **The AAFP commends CMS for proposing requirements to improve access to behavioral health services in MA and address barriers to care caused by prior authorization. As detailed further below and in addition to other recommendations, the AAFP urges CMS to:**

- **Finalize proposals to strengthen MA network adequacy requirements and standards with respect to behavioral health professionals and services.**
- **Encourage MA organizations to implement policies, procedures, and clinician payment structures that support the integration of behavioral health into the primary care setting.**
- **Finalize proposals to improve equitable, timely access to care by improving MA coverage criteria, increasing transparency of prior authorization and medical necessity determinations, and preventing inappropriate coverage denials by MA organizations.**
- **Expand upon and strengthen the proposed rule to address the high volume of prior authorization requests and resulting care delays in MA.**
- **Expand the prior authorization proposals in this rule to prescription drugs and Part D plan sponsors.**
- **Finalize the proposal to require implementation of the Real Time Prescription Benefit standard to make prescription drug coverage information available to the prescribing physician at the point of care.**



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***Health Equity in Medicare Advantage (§§ 422.111, 422.112, and 422.152)***

MA organizations are required to provide culturally competent care, and CMS maintains examples of populations that may require additional considerations such as enrollees with limited English proficiency, limited education, or other socioeconomic disadvantages. CMS is proposing to extend this list to include people:

(1) with limited English proficiency or reading skills;
(2) of ethnic, cultural, racial, or religious minorities;
(3) with disabilities;
(4) who identify as lesbian, gay, bisexual, or other diverse sexual orientations;
(5) who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex;
(6) who live in rural areas and other areas with high levels of deprivation; and
(7) otherwise adversely affected by persistent poverty or inequality.

The AAFP supports access to person-centered, culturally competent health care for all individuals and opposes patient discrimination "on the basis of actual or perceived race, color, religion, gender, sexual orientation, gender identity, ethnic affiliation, health, age, disability, economic status, body habitus or national origin." The AAFP agrees that this extended list is useful in clarifying the populations MA organizations must accommodate to meet requirements for access to services.

MA organizations already maintain searchable provider directories to help connect patients with care. CMS is proposing to codify that this directory include languages spoken and office/location accessibility notes. The AAFP supports the proposal to require MA directories to include information such as languages spoken and accessibility considerations, such as accommodations for individuals with disabilities. These are crucial factors for patients to ensure that physician practices and other facilities are equipped to provide accessible, inclusive, person-centered care. Requiring reporting of these data elements could also aid MA organizations in identifying accessibility gaps in their networks.

CMS is also proposing for directories to indicate providers who are waived to prescribe medications for opioid use disorder (MOUD) such as methadone, buprenorphine, naltrexone, naloxone, or Suboxone. The AAFP notes that the x-waiver to prescribe buprenorphine was removed after this proposed rule was released, and there is additional movement to make naloxone more widely available. While prescribing other MOUDs like methadone is subject to additional regulations, the AAFP is pleased that more physicians and clinicians can prescribe buprenorphine when a patient affirmatively screens for opioid use disorder (OUD) and that naloxone may be more accessible for laypersons who are regularly around individuals likely to experience an opioid overdose. The AAFP agrees with the original intent of this proposal and appreciates CMS allocating time and resources to addressing the overdose epidemic in the U.S. **CMS should instead require MA organizations to note in the directory which clinicians are OUD treatment providers to ensure patients are connected to physicians with appropriate training and specialization.** MA organizations should develop a process for identifying and verifying individual clinicians as OUD treatment providers without imposing additional burden on physician practices, such as by using claims data.

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

Behavioral Health Specialties in Medicare Advantage (MA) Networks (§§ 422.112 and 422.116)

CMS proposes to add clinical psychologists, licensed clinical social workers, and prescribers of medication for opioid use disorder (MOUD) as specialty types that will be evaluated as part of the network adequacy reviews. CMS proposes to include Opioid Treatment Programs and clinicians with an X-waiver as prescribers of MOUD. CMS proposes to set time and distance standards for all three of these specialty types using the same methodology it has used for other types of clinicians. CMS also proposes to make these new specialty types eligible for the 10-percentage point telehealth credit as currently allowed.

**The AAFP supports these proposals.** Primary care practices often rely on behavioral health specialists, like psychologists and social workers, when integrating behavioral health care in the primary care setting or when making referrals for more complex mental health needs. However, the behavioral health workforce shortage and lack of in-network providers has made it difficult for primary care physicians to work with these specialists. The lack of in-network behavioral health professionals also prohibits many patients in need of behavioral health services from accessing affordable care. Adding these specialty types to network reviews and setting time and distance standards will help facilitate contracts between MA organizations and these clinicians and will ultimately improve access for MA beneficiaries.

Moreover, ensuring robust access to MOUD prescribers is essential for improving equitable access to life-saving OUD treatment. We have previously encouraged CMS to create separate, explicit access standards for SUD treatment to ensure patients can access these services in a timely manner. **We applaud CMS for strengthening these standards across programs and strongly support this proposal.**

The AAFP again notes that Congress eliminated the X-waiver for the prescribing of buprenorphine in the Consolidated Appropriations Act, 2023. As such, CMS should modify the definition for prescribers of MOUD in the final rule to include clinicians with a valid DEA license who are willing and able to initiate buprenorphine treatment for patients with OUD.

Given the limited behavioral health workforce and the robust evidence-base supporting telehealth for mental health care, including for MOUD, the AAFP supports policies that improve coverage of and access to tele-mental health services. **CMS should encourage MA organizations to implement processes to ensure beneficiaries are receiving high-quality, person-centered, continuous tele-mental health care, particularly when care is being provided by a direct-to-consumer telehealth company. MA organizations should also require tele-mental health and behavioral health professionals providing services in-person to coordinate with beneficiaries' usual source of primary care.**

Behavioral Health Services in Medicare Advantage (MA) (§§ 422.112 and 422.113)
CMS proposes to extend current requirements for MA organizations to establish programs to coordinate covered services with community and social services to behavioral health services programs to close equity gaps in treatment between physical health and behavioral health. The AAFP strongly supports these proposals and agrees that care coordination is essential for both mental and physical health.

CMS proposes to clarify that some behavioral health services may qualify as emergency services, and, therefore, must not be subject to prior authorization. **The AAFP supports this clarification and agrees that family physicians and behavioral health professionals providing emergency or**

**stabilization behavioral health services should not face prior authorization requirements that ultimately delay necessary care. The AAFP urges CMS to clarify in the final rule that the initiation and continuation of MOUD treatment can qualify as an emergency service under this requirement and therefore should not be subject to prior authorization when prescribed or provided on an emergency basis.** As CMS noted in other sections of the proposed rule, MOUD treatment can be lifesaving and prevent overdose. We believe this scenario fits within the prudent layperson standard CMS sets forth in the proposed rule and should be noted in the final rule.

Medicare Advantage (MA) Access to Services: Appointment Wait Time Standards (§ 422.112)
CMS proposes to codify standards for wait times that apply to both primary care and behavioral health services. These proposed standards are already included in existing guidance on reasonable wait times for primary care visits: 1) urgently needed or emergency services should be immediately accessible; 2) non-urgent services that require medical attention should be accessible within one week; 3) routine and preventive care should be available within 30 days.

CMS seeks comment on whether it should apply other appointment wait time standards for MA organizations, such as those established for qualified health plans (QHPs). The appointment wait time standards for QHPs include: Behavioral health appointments must be available within 10 business days, Primary care (routine) must be available within 15 business days; and Specialty care (non-urgent) must be available within 30 business days. Under this proposal, the wait time requirements would be applicable to primary care and behavioral health specialty types. Finally, CMS seeks comment on whether a more flexible approach to wait time standards should apply to MA organizations.

**The AAFP strongly supports the proposal to codify appointment wait time standards for primary care and behavioral health services in MA.** Appointment wait time standards help advance timely access to care, in addition to other standards that are designed to ensure geographic availability. **The AAFP supported the existing appointment wait time standards for QHPs and would support CMS applying those standards to MA organizations. These standards are more specific than the standards currently outlined in MA guidance and therefore are more likely to drive more robust MA networks and timely access to both behavioral health and primary care services.**

Reports and anecdotes from news outlets and our members indicate that beneficiaries are experiencing significant delays in appointment wait times for behavioral health, primary care, and specialty services. We recognize that some of these challenges are caused by health care worker shortages and the AAFP continues to advocate for several legislative and regulatory policies to help ameliorate those shortages. However, **we urge CMS to use its authority to address these challenges across Medicare, Medicaid, CHIP, and QHP programs, including by implementing specific federal appointment wait time standards for these services.**

In addition to facilitating access to tele-mental health services, advancing the integration of behavioral health care in the primary care setting is one essential, effective strategy for improving beneficiaries' timely, affordable access to behavioral health services. Behavioral health worker shortages and access challenges, coupled with an increasing, urgent need for behavioral health care in the United States, has resulted in many patients relying on their usual source of primary care for addressing behavioral health concerns. Family physicians and other primary care clinicians report that identifying and managing common behavioral health conditions and challenges are an integral part of

comprehensive person-centered primary care. Behavioral health integration allows for greater care coordination, medication management, and warm handoffs between family physicians and behavioral health professionals. However, our members report several challenges to integrating behavioral health in their practices. In addition to a shortage of behavioral health professionals, clinician payment systems do not provide adequate support for the start-up costs associated with behavioral health integration. CMS has recently recognized the value of integrated behavioral health services and taken several meaningful steps to promote it across programs. **The AAFP appreciates CMS' partnership and urges CMS to use its authority in MA to encourage MA organizations to implement policies, procedures, and payment structures that increase investment in and technical support for the integration of behavioral health in the primary care setting.**

***Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, 422.138, and 422.202)***

**The AAFP appreciates and applauds CMS for addressing the issue of prior authorization and other utilization management (UM) processes in MA, which cause barriers to care and delay care for enrollees.** Approximately 45 percent of Medicare beneficiaries are enrolled in a MA plan. Annual CMS audits of MA organizations have revealed widespread and persistent problems related to inappropriate denials of services and payment. A 2022 report from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) confirmed that MA plans sometimes deny prior authorization and payment requests that meet Medicare coverage rules by using clinical criteria not in Medicare coverage rules and requesting unnecessary documentation, as well as making errors. Among these denials, only 13 percent actually met Medicare coverage rules.

Denying requests that meet Medicare coverage rules may prevent or delay beneficiaries from receiving medically necessary care and impose significant administrative burden on physicians and other clinicians. These denials also run directly counter to federal statute, which requires MA plans to provide enrolled beneficiaries with the same benefits they would receive in traditional Medicare. **The AAFP agrees with CMS that guardrails are necessary to ensure that UM processes like prior authorization are used appropriately and ensure timely access to medically necessary care, rather than inhibit patient access to care.**

Physicians have noted that prior authorization requirements are continually increasing, taking time away from providing quality care to their patients and imposing significant, time-intensive and cumbersome administrative tasks on physicians, which also contributes to burnout among physicians. According to an American Medical Association (AMA) survey, 85 percent of physicians report that the burden associated with prior authorization is "high" or "extremely high" and 30 percent of physicians report that prior authorization has led to a serious adverse event for a patient in their care. The survey reports that physicians and their staff spend almost two business days each week completing an average of 40 prior authorizations per physician, per week.

The AMA survey also highlights the impact of prior authorization on patients: 90 percent of physicians say that prior authorization somewhat or significantly impacts patients' clinical outcomes. Furthermore, 79 percent of physicians report that issues related to prior authorization can at least sometimes lead to patients abandoning their recommended course of treatment while 94 percent of physicians report care delays associated with prior authorization. These delays increase wait times for medical services and prescriptions for patients while diminishing access to timely care.

We are hopeful these proposals will result in a lower volume of prior authorization requirements overall, which the AAFP has long called for. The administrative burden and resulting care delays cannot be eliminated or meaningfully reduced without a reduction in the volume of prior authorizations and a more strategic, evidence-based process for qualified prior authorizations. **The AAFP is eager to work with CMS to expand upon these proposals to more comprehensively address the barriers to care and burdens of prior authorization and other UM processes.**

The AAFP notes that this rule does not apply several prior authorization proposals to Part D plan sponsors or prescription drugs. Family physicians continually report that prior authorization requirements for prescription drugs are a significant, if not the greatest, contributor to their overwhelming administrative workload. They also note that such requirements prevent patients from initiating treatment in a timely manner, causing care delays, worsening symptoms, and increasing patient frustration and distress. **We strongly urge CMS to extend the proposals below to prescription drug prior authorizations and Part D plan sponsors and propose additional requirements to address the use of prior authorization in this area in future rulemaking.**

Family physicians have observed an increase in the number of peer-to-peer consultations they must participate in to receive approval for prior authorization requests. These are often executed after multiple attempts to receive approval by administrative practice staff. Often, family physicians can obtain approval in a peer-to-peer consultation using the exact same information and data that their administrative staff presented to the insurer, indicating that the peer-to-peer conversation was an unnecessary administrative hurdle. As detailed below, our members also report that physicians that conduct peer-to-peers on behalf of health insurers often do not have the requisite medical expertise to make decisions about their patients' care. **The AAFP urges CMS to develop guidelines and requirements around the appropriate use of peer-to-peer consultation requirements by MA organizations, including by limiting their overall volume.**

Coverage Criteria for Basic Benefits

MA organizations are required to cover all Part A and B benefits (excluding hospice and kidney acquisition) on the same conditions that items and services are furnished in Traditional Medicare. CMS proposes to codify existing policy that MA organizations must make medical necessity determinations based on coverage and benefit criteria that are no more restrictive than Traditional Medicare's coverage criteria found in national coverage determinations (NCD), local coverage determinations (LCD), and Medicare statutes and regulations. This means that when an MA organization is making a coverage determination on a Medicare covered item or service, the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in Traditional Medicare coverage policies.

The AAFP strongly supports these proposals. We agree these proposals are consistent with existing statutory requirements for MA organizations to provide equal coverage of basic Medicare benefits. The AAFP strongly supports the prohibition on making a coverage or payment determination based on a Medicare covered item or service using internal, proprietary, or external clinical criteria not found in Medicare coverage policies. **We are hopeful that these proposals will advance equitable access to care and transparency in MA coverage policies, and we urge CMS to finalize these proposals.**

CMS notes in the preamble of the proposed rule that the agency "expect[s] MA organizations to make medically necessary decisions in a manner that most favorably provides access to services for beneficiaries and aligns with CMS's definition of reasonable and necessary in the Medicare Program Integrity Manual, Chapter 13, section 13.5.4. This expectation applies to coverage determinations made before the item or service is provided (precertification/prior authorization), during treatment (case management), or after the item or service has been provided (claim for payment)." **The AAFP appreciates CMS including case management and claim payment in this statement, in addition to prior authorization. We wholeheartedly agree that MA organizations should make medical necessity determinations with the goal of providing access to services, including by ensuring physicians and other care providers are paid in a fair and timely manner.** We are concerned that some MA organizations may increase claim and payment denials after the implementation of new prior authorization requirements and regulations. The AAFP encourages CMS to reiterate this expectation in manuals and other program guidance for MA organizations and conduct oversight to prevent an uptick in claim denials if and when these proposals and finalized and implemented.

CMS does not propose to change regulations which enable MA organizations to implement step therapy protocols for Part B drugs. Part B drugs are generally purchase and directly administered by physicians and other clinicians, instead of being prescribed by a clinician and dispensed by a pharmacy. CMS believes that the current step therapy regulations enable MA organizations to negotiate lower prices for Part B drugs and, in turn, lower beneficiary cost sharing. Current regulations state that step therapy and other UM policies may not be used as an unreasonable means to deny coverage of medically necessary services or eliminate access to medically necessary Part B drugs. However, CMS notes that it has not authorized the use of step therapy practices for Part A and Part B (non-drug) items or services and that the proposals in this rule will limit their application for non-drug covered items or services that are basic Medicare benefits.

**The AAFP urges CMS to reconsider its proposal and apply additional guardrails to the use of step therapy for Part B drugs, if the agency will continue to allow its use.** Studies have shown that step therapy worsens adherence to treatment protocols and can lead to additional utilization of outpatient visits, hospitalizations, and other services that ultimately offset cost savings to the health care system (and likely the beneficiary).[1,2,3,4] AAFP policy states that generic medications should not be subject to step therapy, in addition to medications that are already effectively controlling a patient's condition. We urge CMS to examine adding guardrails to ensure that step therapy does not lead to worse patient outcomes.

In situations when no applicable Medicare statute, regulation, NCD, or LCD establishes whether an item or service must be covered, CMS proposes that an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. If an MA plan creates their own internal coverage criteria, they must provide a publicly accessible summary of the evidence used and rationale that supports the coverage criteria.

**The AAFP strongly supports proposals to make criteria for medical necessity and coverage determinations more transparent and clinically valid.** Implementing consistency and specificity of allowable coverage criteria will ensure transparency for decisions regarding beneficiaries' care. This will also allow managing physicians, patients, and other stakeholders to examine and discuss the reasoning provided by the MA organization. This will lead to improved access to evidence-based care for beneficiaries.

**We have several recommendations for expanding upon and strengthening this proposal:**

- **The AAFP urges CMS to apply this proposal to prescription drugs and Part D plan sponsors.** Coverage criteria for prescription drugs should also be transparent and based on widely available treatment guidelines or clinical literature.
- **We further recommend CMS require MA organizations to make summaries and explanations of medical necessity and coverage determination policies prominent and easy to find on a publicly available website.** Patients and their clinicians dealing with prior authorization requirements and denials should not have to spend more time logging into a portal or searching through a plan's website to find the coverage criteria it is using for each service. Such information should be easy to find on the plan's main webpage.
- Along the same lines, **CMS should require MA organizations to provide a link to the publicly available clinical criteria it used when denying a prior authorization request.**
- **CMS should also require MA organizations to provide potential enrollees with a link to its available coverage criteria summaries so that they understand what restrictions to their care they may experience should they enroll in that MA plan.** Potential MA enrollees should have a full and complete understanding of the limits imposed on their health coverage and benefits before enrolling in a plan.
- Finally, **the AAFP strongly recommends CMS require MA plans to involve a physician of the relevant medical specialty in the development of medical necessity and clinical criteria policies it will use to approve or deny coverage of services.** Involving a physician with the relevant medical expertise will help ensure policies are consistent with the available evidence and are appropriate and consistent with current medical practice.

CMS proposes to codify existing standards for individual medical necessity determinations by MA organizations. The proposed regulatory language would require that the medical necessity of plan-covered services be based on coverage policies discussed above; involvement of the plan's medical director, where appropriate; and the enrollee's medical history, physician recommendations, and clinical notes. CMS seeks comment on when the plan's medical director should be involved.

The AAFP supports this proposal. Medical necessity determinations should always be made in context of the enrollee's individual circumstances, clinical presentation, medical history, and importantly, the physician's recommendation. Family physicians using appropriate clinical knowledge, training, and experience should be able to prescribe and order treatment without being subject to prior authorizations. They should also be paid for the services provided in a fair and timely manner.

**The AAFP urges CMS to require MA organizations to consult with a physician of the relevant medical specialty when developing policies for prior authorization and making individual medical necessity determinations across various services and conditions. CMS should also require MA plans to consult a physician of the relevant specialty when reviewing prior authorization requests.** Family physicians regularly report that existing prior authorization processes, including those that require them to have a "peer-to-peer" consultation with another physician, are often dictated by physicians employed by insurers who do not have the requisite expertise to make decisions about patient care. This lack of expertise in family medicine and/or in caring for patients with particular conditions results in erroneous denials, lengthy patient care delays, and additional time spent submitting appeals. Requiring prior authorization requests be handled by

physicians of the same specialty or who have sufficient expertise caring for patients with similar conditions will help prevent unnecessary negative impacts on patients and their physicians.

Appropriate Use of Prior Authorization

CMS notes that all services, except for emergency and urgent services, covered by MA coordinated care plans may be subject to prior authorization. CMS proposes new regulations to provide that a coordinated care plan may use prior authorization processes for basic benefits and supplemental benefits only when the prior authorization meets the following standards. CMS proposes to codify the standard that appropriate prior authorization should only be used to confirm the presence of diagnoses or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary, or, for supplemental benefits, clinically appropriate and should not function to delay or discourage care.

**The AAFP opposes the proposal to provide in new regulations that a coordinated care plan may use prior authorization for basic benefits and supplemental benefits but we agree that appropriate prior authorization should not be a tool used to delay or discourage care.** While we agree that prior authorization should not function to delay or discourage care, we note that the examples provided in the preamble of allowable prior authorizations are indeed likely to delay and discourage care. Family physicians regularly report that it often takes an extended period of time for MA organizations and other insurers to respond to prior authorization requests. This results in delayed care for beneficiaries, even if the stated purpose of the prior authorization requirement was to confirm the presence of a diagnosis or other medical criteria.

**Physicians undergo years of medical training to learn how to properly diagnose conditions and create care plans in consultation with their patients. Prior authorization requirements to confirm these diagnoses are unnecessary and, unless a decision is provided in real time, will always function to delay care.** As currently worded, this proposal empowers MA organizations to require prior authorization to confirm every diagnosis or other medical criteria before agreeing to cover and pay for a service. While this rule includes several proposals preventing MA organizations from ultimately denying coverage of needed services, this proposal still enables MA organizations to require review and approval of nearly every decision a physician makes. This process requires physicians to submit prior authorization requests, which are burdensome and require time to develop and submit. The patient and physician then must wait for the MA organization to receive and review the request before moving forward with a treatment plan. This means that care will be consistently delayed. **The AAFP strongly opposes this proposal and we urge CMS not to finalize it as proposed.**

**CMS should acknowledge in the final rule that prior authorization requirements regularly delay care and, therefore, should rarely be used by coordinated care plans for basic Medicare benefits. In future rulemaking, CMS should impose additional guardrails on the volume of prior authorization requirements that can be imposed.** This could be achieved by creating limits on the use of prior authorization for certain benefit categories or low-cost services. **In the meantime, CMS should encourage MA plans to develop programs and exception policies that limit the volume of prior authorization for services that are considered standard of care.** We provide further discussion of gold carding programs below.

**CMS should also outline explicit requirements for MA organizations to respond to prior authorization requests in a timely manner: 24 hours for urgent requests and 48 hours for non-**

**urgent requests.** These standards for response will help ensure prior authorization requirements imposed by MA organizations do not significantly delay care. While we recognize that another proposed rule includes timeframes in which MA organizations and other payers must respond to electronic prior authorization requests, more explicit standards are urgently needed before these requirements are implemented in 2026.

Continuity of Care

CMS proposes to require MA plans to allow all approved prior authorizations to be valid for the entire course of treatment. CMS also proposes to require MA plans to provide a minimum 90-day transition period for any ongoing courses of treatment when an enrollee currently undergoing treatment switches to a new MA plan. This means that for a minimum of 90 days, when an enrollee switches to a new MA coordinated care plan, any active course of treatment must not be subject to any prior authorization requirements

**The AAFP strongly supports these proposals and appreciates CMS' efforts to ensure that prior authorization requirements do not impede care continuity.** Prior authorization processes often require enrollees to interrupt ongoing treatment and undergo repetitive approvals for needed services that were previously approved, unnecessarily delaying or preventing access to the treatment plan their physician prescribed. The AAFP recommends CMS apply this requirement to the entire ordered course of treatment. Ensuring prior authorizations are valid for the entire course of treatment and implementing a 90-day transition period for enrollees switching plans will help avoid delayed care and patient confusion, preserve trust in the patient-physician relationship, and increase adherence to prescribed treatment.

Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee

CMS is proposing to require MA organizations to establish a Utilization Management (UM) committee, led by the MA plan's medical director, to review UM policies and procedures annually and ensure consistency with traditional Medicare's national and local coverage decisions and guidelines. CMS proposes the committee must include a majority of members who are practicing physicians with representation of various clinical specialties, including primary care. CMS proposes that the committee must revise UM policies and procedures as necessary, and at least annually, to comply with standards in the regulation. CMS seeks comment on expanding this proposal.

The AAFP supports this proposal and applauds CMS for requiring the committee to include physicians representing a variety of specialties, including primary care. Family physicians offer a unique perspective as they are trained to provide a broad scope of medical services, order and interpret tests in the context of the patient's overall health condition, and develop evidence-based and tailored treatment plans. Family physicians also practice in a variety of settings (I.e. clinics, inpatient hospital services, emergency departments, urgent care facilities, skilled nursing facilities) and care for patients across the lifespan. **The AAFP urges CMS to require that UM policies and procedures are developed in consultation with contracted providers. CMS should require the MA organization to communicate new UM policies to contracted providers and enrollees in a timely manner. As previously noted, the AAFP strongly recommends CMS require MA organizations to consult a physician of the relevant specialty when developing all prior authorization and medical necessity policies and reviewing individual prior authorization requests.**

Enforcement

We urge CMS, in the final rule, to include how enforcement of these new prior authorization requirements for MA organizations will be conducted. CMS should use its authority to deny an MA organization's application to participate in MA if that organization is not in compliance with the prior authorization requirements outlined here. However, CMS should also outline a process for identifying and addressing problematic prior authorization practices by an MA organization. This could include a process for patients to easily and quickly self-report care delays caused by prior authorization and other UM processes. Enforcement should not solely rely on physicians reporting violations by plans as this is an additional administrative burden on physicians that takes time away from patient care.

Gold Carding

Some MA plans relieve certain providers from prior authorization requirements based on consistent adherence to plan requirements, appropriate utilization of items or services, and other evidence-driven criteria. CMS believes the use of gold-carding programs could help alleviate the burden associated with prior authorization and that such programs could facilitate more timely access to care for enrollees, and CMS encourages MA plans to adopt gold-carding programs.

The AAFP is supportive of policies like gold carding that reduce the volume of prior authorizations. However, there are several considerations for implementing these programs to ensure they successfully reduce care delays and administrative burden. The AAFP believes CMS should take into account the broad-scope, comprehensive care that family physicians deliver when considering gold carding threshold requirements. Due to the breadth of this care, it may be difficult for family physicians to meet the minimum threshold for orders of each service to qualify for the gold card. Physicians who provide more subspecialized care are more easily able to meet gold carding thresholds. The outcome could be that specialists benefit from gold carding programs while family physicians are excluded due to these requirements. Given that family physicians are more likely to practice in rural and other underserved areas, this would result access disparities and additional barriers to care for already underserved populations.[5]

Primary care physicians manage a wide range of health conditions requiring medications for a broad spectrum of diseases. Most family medicine practices participate with or seven or more insurance companies which necessitates navigating each payer's rules and processes. As we've repeatedly noted, obtaining prior authorizations for medications is time consuming and burdensome for family physicians. The AAFP believes medications should be included in gold carding programs in addition to procedures, testing, and durable medical equipment. Not including drugs in gold carding programs would significantly diminish the positive impact on family physicians and their patients.

We look forward to discussing these considerations and guardrails for the implementation of gold carding programs in MA for future rulemaking.

Real Time Prescription Benefit

CMS proposes to require Part D plan sponsors to comply with the National Council for Prescription Drug Programs' (NCPDP) Real-Time Prescription Benefit standard version 12, which enables the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identifies coverage restrictions and alternatives when they exist. **The AAFP strongly support this proposal. The widespread adoption of the Real Time Prescription Benefit standard would allow physicians to check prior authorization requirements and drug**

**formulary status at the point of prescribing in EHRs.** This is consistent with AAFP policy which notes that physicians must have real-time information made available to them about drug formularies at the point of care. Such information facilitates shared decision making between physicians and their patients about the best treatments available to them, the cost of those treatments, and associated insurer UM requirements or other restrictions that may require patients to try an alternative. Enabling these conversations at the point of care can help reduce care delays and patient frustration.

As previously noted, **the AAFP urges CMS to apply its proposed clinical validity and transparency of coverage criteria policies to prescription drugs.** AAFP members emphasize that prior authorization requirements for prescription drugs are among the most burdensome UM processes they encounter, causing care delays, worsening patients' adherence to treatment, and imposing an overwhelming amount of administrative work on physician practices. CMS' proposals requiring transparency and clinical validity for non-prescription drug services and encounters are common sense and consistent with federal statute. We strongly urge CMS to apply these requirements to Part D plan sponsors.

Thank you for the opportunity to provide comments on the proposed rule. Should you have any questions, please contact Meredith Yinger, Manager, Regulatory Affairs at myinger@aafp.org or (202) 235-5126.

Sincerely,

Sterling N. Ransone, Jr., MD, FAAFP
Board Chair, American Academy of Family Physicians

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