AMERICAN ACADEMY OF FAMILY PHYSICIANS

December 21, 2023

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

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

**Re: CMS-4205-P: Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; 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 129,600 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 2025 as published in the Federal Register on November 15, 2023.

The AAFP commends CMS for proposing requirements to improve access to behavioral health services and address barriers to care caused by prior authorization in MA. As detailed further below and in addition to other recommendations, the AAFP urges CMS to:

- **Finalize the proposal to update and add network adequacy standards for additional types of behavioral health professionals.**
- **Expand upon the proposal to strengthen network adequacy requirements for outpatient behavioral health by creating separate access standards for substance use disorder services.**
- **Finalize the proposal to adopt updated e-prescribing standards in Part D.**
- **Cross-reference Part D e-prescribing regulation with standards published by the Office of the National Coordinator for Health Information Technology (ONC) to reduce confusion and administrative burden as new standards are released.**
- **Finalize the proposal to require plan Utilization Management (UM) committees include at least one member with health equity expertise and publish an annual health equity analysis on the plan's use of prior authorization.**
- **Collect detailed information from MA and Part D plans to improve transparency about utilization management practices.**
- **Encourage MA plans to submit accurate, complete, and unbiased data on appeals and appeals decisions by modifying provisions of the Star Ratings system.**



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***Expanding Network Adequacy Requirements for Behavioral Health***

Under current regulations, beginning in 2024 MA plans will be required to demonstrate network adequacy for psychiatry, clinical psychology, clinical social work, and inpatient psychiatric facility services. Additionally, MA plans will be required to contract with and cover services by Marriage and Family Therapists (MFTs) and Mental Health Councilors (MHCs) in 2024 because these providers groups are now included in Medicare Part B, but no existing network adequacy standards are in place for these clinicians or their services. There are no existing requirements for coverage and network adequacy of substance use disorder (SUD) or medications for opioid use disorder (MOUD) services.

For plan year 2025, CMS proposes to address concerns over lack of access to SUD and MOUD services and include MFTs and MHCs by requiring plans to meet network adequacy requirements for a combined facility-specialty type, "Outpatient Behavioral Health." This facility-specialty type can include MFTs, MHCs, opioid treatment programs (OTPs), community mental health centers, and practitioners who "regularly furnish or will regularly furnish behavioral health counseling or therapy services, including, but not limited to, psychotherapy or prescription of medication for substance use disorders: physician assistants, nurse practitioners, and clinical nurse specialists (as defined in section 1861(aa)(5) of the Act); addiction medicine physicians; or outpatient mental health and substance use treatment facilities." Organizations are allowed to include the contracted individual practitioners, group practices, or facilities on their facility health service delivery tables for this combined facility-specialty type.

The AAFP agrees that MA plans must ensure appropriate access to behavioral health care, including mental health care, SUD treatment including MOUD, and counseling services. **The AAFP strongly urges CMS to consider adding two different facility-specialty types to better delineate between access to mental health services and access to SUD services.** While we support the inclusion of the above facilities, clinician types, and application of network adequacy standards, the AAFP is concerned that combining OTPs, addiction medicine physicians, and other clinicians who specialize in SUD treatment with other mental health services will overestimate the network adequacy of critically needed SUD services. As of 2022, 17.3 percent of the population had a SUD, yet for individuals 12 and older who were classified as needing substance use treatment in the past year, only one in four received treatment.[1] Of adults who did not receive treatment for an SUD bult felt they needed it, over 52 percent were unsure where to receive treatment and nearly 48 percent were concerned about the cost of treatment.[2] As the SUD and overdose rates continue to rise in the U.S., it is clear CMS should use all available tools to monitor and improve access to treatment, including by separating out SUD services and mental health services in the proposed facility-specialty type. Additionally, with a separate facility-specialty type, CMS should consider more stringent SUD time and distance standards for SUD treatment if access to services continues to fall short of the MA population's need. CMS has already proposed disaggregating data evaluation of mental health and SUD services under Medicaid managed care and CHIP plans, and it should continue under this proposal as well.

The AAFP also recognizes that some family physicians may not be board certified addiction medicine physicians but still specialize in SUD treatment and/or regularly provide MOUD or other SUD services. The AAFP does not advocate for a blanket inclusion of primary care physicians in the proposed "Outpatient Behavioral Health" facility-specialist type, as this would vastly over-estimate MA plans' network adequacy. **However, the AAFP strongly urges CMS to clarify in the list of clinicians for the "Outpatient Behavioral Health" facility-specialty type, that family physicians**

**and other primary care physicians may be included if they regularly provide or specialize in SUD treatment.**

Family physicians also regularly work with psychiatrists, psychologists, social workers, MFTs, MHCs and other behavioral health professionals to provide behavioral health care, often in primary care settings.[3, 4] These mental health professionals are valuable members of physician-led integrated care teams and/or receive referrals from family physicians. As such, CMS' proposal to update and add network adequacy standards for MFTs, MHCs, and SUD facilities for MA plans will help ensure family physicians and other primary care physicians can utilize a care team that best fits the needs of their practice and patient population and refer patients to in-network mental health professionals.

In fact, the 2023 report from the Bureau of Labor Statistics reports that 28% of MFTs work in the offices of other medical professionals, greater than the 13% that work in outpatient settings.[5] Both setting types are important for MA beneficiary access to services by MFTs and MHCs, and we appreciate the clear language including community mental health settings. **The AAFP is interpreting the proposed facility-specialty type to also include primary care practices with integrated behavioral health services that include MFTs, MHCs, and addiction medicine physicians. Given the relatively high rates of MFTs working in other medical professional offices, it may be helpful for CMS to clarify that facilities like integrated primary care practices that regularly provide behavioral health counseling or therapy services are included in the "Outpatient Behavioral Health" facility-specialty type.**

Finally, CMS proposes to allow the 10-percentage point credit for telehealth services under the "Outpatient Behavioral Health" facility-specialty type. As proposed, MA plans would receive a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards when the plan includes one or more telehealth clinicians that provide additional telehealth benefits. The AAFP supports this telehealth credit for behavioral health services, because data shows telehealth and audio-only services are uniquely suited for behavioral health care and other workforce shortages may warrant the need for telehealth visits.[6, 7, 8] Particularly, for SUD treatment, telehealth and audio-only initiation of and continued treatment with buprenorphine was also associated with higher patient satisfaction, lower health care costs, and improved access to treatment.[9]

***Standards for Electronic Prescribing (§ 423.160)***

CMS proposes a requirement to use the updated National Council for Prescription Drug Programs (NCPDP) SCRIPT (standards used to exchange information for e-preSCRIPTions) version 2023011 (and to retire version 2017071) for Part D e-prescribing starting January 1, 2027. CMS also proposes to update other e-prescribing related standards including the adoption of NCPDP Real-Time Prescription Benefit (RTPB) standard version 13 for real-time benefit transactions (RTBT) and the adoption of NCPDP Formulary and Benefit (F&B) standard version 60.

AAFP members have repeatedly expressed prior authorization (PA) requirements for prescription drugs are a significant administrative burden. PA processes force physicians to take time away from patient care to understand arbitrary formulary changes and/or new prior authorization requirements. In recent congressional testimony, AAFP President Dr. Steven Furr described how the lack of transparency around plan formularies and patient coverage negatively impacts patients. Without

access to plan coverage details at the point of prescribing, physicians spend a significant amount of time going back-and-forth with the pharmacy to identify alternative medicines that meet coverage requirements.

The AAFP supported earlier proposals to adopt NCPDP RTPB standards, which enable the real-time exchange of patient-specific coverage (including restrictions and alternatives) and estimated cost-sharing at the point of prescribing. These standards would allow family physicians to understand formulary and prior authorization requirements for patients when writing a prescription. The proposal aligns with AAFP policy stating physicians must have real-time information available about drug formularies at the point of care. We applaud the proposal to adopt RTPB standard version 13 because it offers enhancements that would enable payers to provide additional product-level details about coverage and formulary status.

NCPDP F&B standards enable plans to share formulary and benefit information at the plan level, as opposed to the patient-level eligibility information offered by RTPB standards. These standards allow payers to transmit information about formulary status, preferred alternatives, and coverage restrictions consistent with each plan's benefit design. F&B standards are the foundation of electronic prior authorization (ePA) functionality and real-time benefit checks for individual patients in Part D. We have previously urged CMS to require plans (including Part D plans) to implement ePA standards, and we support the adoption of the proposed F&B standards which will facilitate the use of ePA in Part D plans. Currently, family physicians spend a significant amount of time determining whether a prior authorization is required, and if so, the documentation requirements for approval. We believe this proposal is a foundational step to require Part D plans to implement ePA and make prior authorization requirements more transparent to physicians and their staffs.

The proposed adoption of NCPDP SCRIPT standard version 2023011 provides enhancements to e-prescribing capabilities, including the ability to communicate with Long Term Care (LTC) settings and a new "Pending" reply option for prescribers to use with pharmacy prescription change and renewal requests. We also note that the proposed standard is "backwards compatible;" in other words, the standard will also work with the previous version which means plans, prescribers, and pharmacies will continue to be able to communicate regardless of the adoption timeline they select.

In summary, the AAFP strongly supports these proposals and believes the enhancements more recent versions offer will increase transparency of prior authorization requirements, formulary design, and patient financial responsibility at the point of prescribing. Further, the backwards compatibility of these new standards will support a transition by January 1, 2027. We continue to support the use of ePA standards in Medicare Part D plans and urge CMS to apply these standards to other non-Part D plans.

Finally, while we are encouraged by the adoption of standards to support RTBT, we note that the availability of RTBT tools in physician EHRs varies. As a result, physicians often do not have access to real-time benefits information for all of their patients or for all Part D plans. We encourage ONC and CMS to examine physician use of real-time benefit checks for Part D plans and consider approaches to addressing barriers to widespread physician access to RTBT tools in future regulation.

***Adoption of Health IT Standards and Incorporation by Reference (45 CFR 170.205 and 170.299)***

CMS proposes changes to the regulatory text that will cross-reference Part D e-prescribing requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC). This change will ensure Part D e-prescribing standards are always aligned with the latest required standards for certified electronic health records.

**The AAFP strongly supports the proposal to cross-reference standards used for Medicare Part D e-prescribing with standards adopted by ONC.** In the past, uneven adoption of standards has led to confusion and additional regulatory burden. We applaud CMS for streamlining regulations. We support establishing a single point in the Code of Federal Regulations to allow HHS to codify health IT standards across all programs simultaneously.

***Annual Health Equity Analysis of Utilization Management Policies and Procedures (§ 423.137)***

Beginning January 1, 2024, CMS will require MA plans to establish a Utilization Management (UM) committee to conduct an annual review of all UM policies and procedures. In this rule, CMS proposes the UM committees must include one member with "expertise in health equity" and publish an annual health equity analysis on the use of prior authorization. The report must be posted publicly starting July 1, 2025, and include metrics that compare the use and outcomes of prior authorization between enrollees with certain social-risk factors (SRFs) and enrollees without SRFs.

The AAFP is committed to ensuring access to healthcare for all individuals. However, utilization management policies often prevent enrollees with SRFs from accessing the care they need and that their family physician recommends. **We support the proposed UM committee requirement to include one member with health equity expertise and to publish an annual health equity analysis identifying disparities in the plan's use of prior authorization.**

There is growing concern about the impact of prior authorization processes in Medicare Advantage plans. A 2018 OIG report found that MA plans overturned approximately 75% of denied prior authorizations on appeal.[10] A more recent 2023 OIG report found that 13% of MA denials met the requirements of Medicare coverage rules; in other words, 13% of the services should have been approved.[11] In addition to increasing administrative burden for physicians, these unwarranted denials often prevent or delay beneficiary treatment.

Additionally, there is evidence prior authorization denial rates are significantly higher in Medicaid managed care plans compared to Medicare Advantage.[12] Many Medicaid managed care enrollees report that many do not understand their rights or their ability to request an appeal, and the threat of repayment causes beneficiaries to abandon or delay treatment when prior authorizations are denied.[13] **The AAFP supports CMS' proposal to require plans to examine and report prior authorization (PA) data for dual-eligibles and those enrolled in Medicare due to disability.**

**The AAFP also supports CMS's proposal to make the health equity analyses publicly available, easily accessible, and in a format that will enable researchers to further analyze the results.** We encourage CMS to consider aggregating PA data from multiple analyses into a single file to enable greater analysis and comparison across plans. Access to PA data will provide researchers

with a valuable source of data to identify and address health disparities and equip enrollees and their caregivers with accurate data on access to care across plans.

**The AAFP urges CMS to expand this proposal to require MA plans disaggregate PA data by service, in addition to SRFs.** Otherwise, it will be difficult to identify actionable next steps to resolve reported health inequities. For example, knowing a population is more likely to experience delays or denials for a specific service will allow plans to target their efforts to reduce health inequities more effectively.

CMS is also requesting comment on additional populations CMS should consider including in the health equity analysis, such as certain racial or ethnic communities, LGBTQ+ communities, limited English proficiency, rural communities, and other communities adversely affected by poverty or inequality. **We support robust health equity analyses that extend beyond the SRFs identified in this proposal.** However, we recognize that not all populations can be reliably identified using available data elements. A recent report from the CMS Office of Minority Health (OMH) found that while data about enrollee race and ethnicity is available for MA, sexual orientation and gender identity data (SOGI) is not collected in a standardized way.[14]

The AAFP strongly supports CMS' commitment to improving health care data with the goal of better identifying and addressing health disparities. **We encourage CMS to require that plans report on as many SRF populations as MA data currently allows. CMS should continue to support the capture and standardization of SRF data elements in MA data and update SRF reporting requirements when new data elements are available.**

***Amendments to Part C and D reporting requirements (§§ 422.516 and 423.514)***

CMS proposes to clarify the types of data the agency may require plans to report. In addition to performance metrics summarizing the outcomes of utilization management processes, CMS proposes clarifying their authority to collect policies and procedures used to make utilization and coverage decisions.

**The AAFP supports the proposal to affirm CMS' authority to collect detailed information from MA organizations and Part D plans about utilization management**, and strongly supports any future efforts to collect information regarding coverage decisions and utilization, including beneficiary requirements to access coverage. CMS clarified in the 2024 MA rule that plans must make medical necessity determinations based on the individual, as opposed to using algorithms or artificial intelligence. However, we are concerned with recent reports indicating the widespread use of algorithms that do not make necessity determinations based on the individual.[15] We encourage CMS (and HHS and OIG) to collect information about the plan's use of algorithms or artificial intelligence (AI) in utilization management decisions.

***Data Integrity (§§ 422.164(g) and 423.184(g))***

MA and Part D plans are required to report data on their coverage appeals processes as part of the Star Ratings Program. We applaud CMS' proposal to encourage plans to use complete and accurate data when reporting measures related to the appeals process. CMS proposes that plans must report

complete, accurate, and unbiased information about their appeals process which is used to validate the accuracy of the plan-submitted appeals measures. When plans fail to submit complete data, CMS proposes a formula to make scaled adjustments to the plan's Star Ratings score. **We support CMS' proposal to identify data completeness issues and to calculate scaled reductions to encourage complete and accurate reporting of Part C appeals data and related measures.**

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions or need additional information, please contact Julie Riley, Regulatory and Policy Strategist at jriley@aafp.org.

Sincerely,

Tochi Iroku-Malize, MD, MPH, MBA, FAAFP
American Academy of Family Physicians, Board Chair

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[1] Substance Abuse and Mental Health Services Administration. (2023). Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health (HHS Publication No. PEP23-07-01-006, NSDUH Series H-58). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report

[2] Ibid.

[3] Clatney L, MacDonald H, Shah SM. Mental health care in the primary care setting. Can Fam Physician. 2008;54(6):884 LP - 889. http://www.cfp.ca/content/54/6/884.abstract

[4] Clark, R.E., Linville, D. and Rosen, K.H. (2009), A National Survey of Family Physicians: Perspectives on Collaboration With Marriage and Family Therapists. Journal of Marital and Family Therapy, 35: 220- 230. https://doi.org/10.1111/j.1752-0606.2009.00107.x

[5] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Marriage and Family Therapists, at https://www.bls.gov/ooh/community-and-social-service/marriage-and-family-therapists.htm (visited *November 01, 2023*).

[6] Nordeck, C. D., Buresh, M., Krawczyk, N., Fingerhood, M., & Agus, D. (2021). Adapting a Low-threshold Buprenorphine Program for Vulnerable Populations During the COVID-19 Pandemic. Journal of addiction medicine, 15(5), 364–369. https://doi.org/10.1097/ADM.0000000000000774

[7] Vakkalanka, J.P., Lund, B.C., Ward, M.M. et al. Telehealth Utilization Is Associated with Lower Risk of Discontinuation of Buprenorphine: a Retrospective Cohort Study of US Veterans. J GEN INTERN MED 37, 1610–1618 (2022). https://doi.org/10.1007/s11606-021-06969-1

[8] Wunsch, Caroline MD; Wightman, Rachel MD; Pratty, Claire MS; Jacka, Brendan PhD; Hallowell, Benjamin D. PhD; Clark, Seth MD; Davis, Corey S. JD, MSPH; Samuels, Elizabeth A. MD, MPH, MHS. Thirty-day

Treatment Continuation After Audio-only Buprenorphine Telehealth Initiation. Journal of Addiction Medicine ():10.1097/ADM.0000000000001077, September 14, 2022. | DOI: 10.1097/ADM.0000000000001077

[9] Aileen G. Guillen, Minal Reddy, Soheil Saadat, and Bharath Chakravarthy, "Utilization of Telehealth Solutions for Patients with Opioid Use Disorder Using Buprenorphine: A Scoping Review." Telemedicine and e-Health 2022 28:6, 761-767. Accessed at: https://www.liebertpub.com/doi/full/10.1089/tmj.2021.0308

[10] https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf

[11] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

[12] https://oig.hhs.gov/oei/reports/OEI-09-19-00350.pdf

[13] https://www.macpac.gov/wp-content/uploads/2023/11/Improving-the-Managed-Care-Appeals-Process.pdf

[14] https://www.cms.gov/files/document/path-forwardhe-data-paper.pdf

[15] Beth Mole, "UnitedHealth uses AI model with 90% error rate to deny care, lawsuit alleges," ArsTechnica, November 16, 2023. Available: https://arstechnica.com/health/2023/11/ai-with-90-error-rate-forces-elderly-out-of-rehab-nursing-homes-suit-claims/