February 9, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Submitted via regulations.gov

Dear Administrator Brooks-LaSure:

The American College of Osteopathic Internists (ACOI), representing the nation's osteopathic internists, medical subspecialists, fellows, residents, and students, welcomes the opportunity to provide comment on several policies included in the Centers for Medicare and Medicaid Services' (CMS') proposed rule, *Contract Year 2024 Policy and Technical Changes to Medicare Advantage (MA) Program (Part C) and Medicare Prescription Drug Benefit (Part D), etc.* [CMS-4201-P]. ACOI offers comment on the following sections of the rule:

- 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
- Review of Medical Necessity Decisions
- Changes to an Approved Formulary

Utilization Management Requirements

Among the greatest barriers to access to care is prior authorization. According to a 2021 survey of physicians conducted by the American Medical Association (AMA), 93 percent reported that prior authorization (PA) delays access to necessary care. Moreover, 82 percent reported that PA can at least sometimes lead to treatment abandonment.

PA requirements also divert time away from patients. The AMA survey found that practices complete 41 PAs on average per physician, per week. Physicians should be focused on patient care and not on navigating the PA process to get patients their recommended tests, procedures, and treatments.

Denials of PA requests are raising concerns about beneficiary access to medically necessary care. The Office of the Inspector General (OIG) released a report last year that found, upon examination of a random sample of 250 PA denials by MA plans, 13 percent met Medicare coverage rules and likely would have been approved for these beneficiaries under original Medicare.

The burden of PA has only worsened as beneficiary enrollment in MA plans has steadily climbed, reaching nearly half of the Medicare eligible population in 2022. Regulatory actions are urgently needed to ease the burden of PA on physician practices and to ensure that America's seniors have timely access to care.

Coverage Criteria for Basic Benefits — To ensure minimum coverage requirements are met and that MA plan enrollees are not impeded in accessing basic benefits to which they are entitled, ACOI urges CMS to finalize the following proposals:

- Codify existing standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than traditional Medicare;
- Prohibit MA organizations from denying coverage of an item or service based on internal, proprietary, or external clinical criteria not found in traditional Medicare coverage policies; and
- When coverage criteria are not fully established in applicable Medicare statute, regulation, National Coverage Determination (NCD), or Local Coverage Determination (LCD), 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.

CMS should also strengthen its PA reform efforts by extending its proposed clinical validity and transparency of coverage criteria polices into the area of prescription drugs.

Medical Necessity Determinations — Although CMS has longstanding guidance interpreting the obligations of MA organizations when making medical necessity determinations, the OIG found that CMS guidance is not sufficiently detailed and recommended that CMS issue new guidance on the appropriate use of MA plan clinical criteria in medical necessity reviews. ACOI supports CMS' proposals to codify and clarify existing standards to ensure that MA plans furnish all reasonable and necessary Part A and B benefits and that coverage criteria used by MA plans is consistent with coverage criteria in Medicare statutes, regulations, NCDs and LCDs.

Appropriate Use of Prior Authorization — ACOI agrees with CMS that appropriate PA 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. Further, ACOI supports codification of existing guidance that currently states that if a plan approved the furnishing of a service through an advance determination of coverage, it may not deny coverage later based on the lack of medical necessity.

Continuity of Care — ACOI appreciates CMS' acknowledgement that when MA plans require repetitive prior approvals for ongoing treatments, enrollees may face delays in receiving medically necessary care or experience gaps in care delivery that threaten an enrollee's health and safety. ACOI asks CMS to finalize the following proposals to protect patients, especially those with chronic conditions, from care interruptions, treatment delays, and unanticipated medical costs:

- All approved PAs must be valid for the duration of the entire approved prescribed or ordered course of treatment or service (including scheduled procedures regardless of whether there are specific visits or activities leading up to the procedure). It is important that PAs be valid for the active course of treatment, so physicians do not have to repeatedly obtain PA when re-ordering drugs or biologics for patients in active treatment for chronic conditions. As an example, ACOI members cite that it is becoming increasingly prevalent for payers to require the reauthorization of medications for organ transplant patients. Others cite having to resubmit for authorization for the treatment of Alpha-1 antitrypsin — a life-long condition. Requirements for repeats authorizations do nothing more than add to physician administrative burden and often delay patient care.
- MA organizations must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days.

Utilization Management Policies — ACOI supports and asks CMS to finalize its proposed procedural improvements to ensure that utilization management (UM) policies are reviewed on a timely basis and have the benefit of provider input. We support that a UM committee must include a majority of members who are practicing physicians and further recommend the committee should include board-certified physicians in every major specialty. When a committee does not include a member with appropriate expertise for reviewing policies for a specific item or service, the committee should be required to consult with a contracted physician(s) who has expertise for a particular item or service.

Step Therapy — ACOI is deeply disappointed CMS has chosen not to address step therapy processes as part of this proposed rule. While we appreciate that utilization management practices are a response to high-cost drugs, patients and providers are caught in the middle. It is time to reign-in the egregious practice of step therapy by health plans starting with reinstatement of the prohibition on MA plans implementing step therapy for all Part B drugs as described in the September 17, 2012, Health Plan Management System memo Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services.

Gold Carding — ACOI supports streamlining the PA processes for prescription medication and medical services through the practice of adjusting PA requirements for providers with high approval rates, also referred to as "gold carding." We appreciate CMS encourages MA plans to adopt gold-carding programs. We believe, however, gold carding programs should be a requirement for MA plans, not an option.

Review of Medical Necessity Decisions

Among the biggest frustrations with the PA process experienced by physicians is the review of medical necessity by clinicians who lack appropriate expertise for the service or item for which authorization is being requested. ACOI supports CMS' proposal to apply the standard of ''expertise appropriate for the specific service at issue'' at the organization determination level in the same manner as plans have applied this standard at the reconsideration level. Lack of appropriate expertise at the initial determination level often leads to denial of services that are ultimately approved on

appeal, resulting in otherwise unnecessary administrative burden and delays in patient care. ACOI urges CMS to finalize this proposal.

Changes to an Approved Formulary

CMS proposes a definition of negative formulary changes as the following changes with respect to a Part D drug: (1) removing the drug from a formulary; (2) moving the drug to a higher cost-sharing tier; or (3) adding or making more restrictive prior authorization, step therapy, or quantity limits requirements for the drug.

ACOI supports this definition and CMS' proposal to codify existing policies with respect to negative changes to approved formularies, including the following:

- Part D plan sponsors must not implement non-maintenance changes until they receive notice of approval from CMS;
- Affected enrollees are exempt from approved non-maintenance changes for the remainder of the contract year; and
- Part D sponsors are prohibited from making certain negative formulary changes between the beginning of the annual election period until 60 days after the beginning of their contract year.

Notice of Negative Immediate Changes — CMS states it is providing more plan flexibility by removing the requirement that alternative drugs must be in the same therapeutic category or class. CMS notes that while alternative drugs are likely to exist, they might not necessarily be in the same therapeutic category or class based on a plan's classification system. CMS is relying on the Part D sponsor's P&T committee to identify clinically appropriate formulary alternatives at the time the formulary change is being evaluated. This proposal raises concern among ACOI members that Part D plans will use this flexibility to switch patients under the automatic substitution rules to therapies in a different class that appear to work equally well but for which there are often subtle, but clinically significant differences between therapeutics — for example, Angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs). We believe there needs to be clear acceptable substitutions to avoid issues with class interchangeability. Further, we are concerned this provision could alter the way a patient receives their medication. For example, could a change in therapeutic class require a patient who receives therapy via self-injection to receive therapy by infusion instead? Individual patient circumstances must be taken into consideration when changes to a formulary could lead to changes in route of administration. For example, does the patient have access to transportation to an infusion center?

Conclusion

Restrictive utilization management tactics have pervaded the health care system. Reviews of medical necessity are inconsistently applied, and physician recommendations are routinely disregarded. According to the Department of Health and Human Services, a record 35 million people are enrolled in coverage related to the Affordable Care Act and 21 million are enrolled in Medicaid expansion coverage. These gains are remarkable, but unfortunately, coverage does not always equal access, or

at least, timely access. Two recently published stories, which have been widely circulated,[1,2] shine a bright light on the extent to which insurance companies are making health care decisions over the recommendations of treating physicians.

The gains in Americans with health coverage coupled with an aging population that trends toward more Medicare beneficiaries is increasing the demand for health care services. At the same time, the Association of American Medical Colleges predicts a shortage of physicians. Physicians need strategies to help meet the demand for services, which must include a reduction in administrative burden associated with PA and other utilization management tactics. Not only do PA and utilization review requirements pose a direct threat to patient safety and outcomes, but also an indirect threat as physicians are forced to dedicate more of their patient-facing time and resources to overcoming these hurdles. Without reform, these factors will effectively amplify the physician shortage. ACOI is grateful for the steps CMS is taking to address the burden of PA on MA beneficiaries and their providers, and we urge the Agency to expand its efforts to all health insurance markets.

Requests for additional information or questions should be directed to Tim McNichol, ACOI Deputy Executive Director at tmcnichol@acoi.org or (301) 231-8877.

Sincerely,

Joanne Kaiser-Smith, DO, FACOI
President, American College of Osteopathic Internists

[1] "I wrote about high-priced drugs for years. Then my toddler needed one." *Washington Post*, Jan. 30, 2023. https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies/

[2] "UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings." *ProPublica*, Feb. 2, 2023. https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis