February 13, 2023

Chiquita Brooks La-Sure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: 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 **[RIN: 0938-AU96]**

Dear Administrator Brooks-LaSure:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) notice of proposed rulemaking regarding Contract Year (CY) 2024 policy and technical revisions to regulations governing Medicare Advantage (MA or Part C), the Medicare Prescription Drug Benefit (Part D), Medicare cost plans, and Programs of All-Inclusive Care for the Elderly (PACE). The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 160,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The College commends CMS for releasing a proposed rule that would increase oversight of MA plans, better align them with traditional Medicare (TM), improve health equity, address access gaps in behavioral services, and further streamline prior authorization processes, supplementing a separate group of proposals from the Agency. Collectively, these are among the most impactful policy changes CMS has proposed to the MA and Part D programs in recent years. As the Agency continues its work to adopt guardrails that best meet the needs of beneficiaries, we are also urging Congress to pass the Improving Seniors' Timely Access to Care Act, which would streamline and standardize prior authorization processes in the MA program.

CMS' proposed changes to the MA program can have wide-ranging implications for the health care industry. According to the Kaiser Family Foundation (KFF), nearly half (48%) of the eligible Medicare population are currently enrolled in a MA plan, accounting for $427 billion (or 55%) of total federal Medicare spending. If projections from the Congressional Budget Office (CBO) remain, the number of enrollees in MA will surpass those in TM by 2025. Changes to the MA program, therefore, will have considerable impact on beneficiaries and physicians.

Enhancements to Medicare Advantage and Medicare Part D

Ensuring Timely Access to Care: Utilization Management Requirements

ACP commends CMS for proposing changes to address concerns about MA programs' use of certain practices and the effect on beneficiary access to care. Through our Patients Before Paperwork initiative, which launched in 2015, the College has consistently raised concerns about the negative effects of certain MA practices, including prior authorization, that have the potential to harm patients through unnecessary care delays. Current prior authorization processes lead to wasted time, resources, and harm to patients. Perhaps most egregious, prior authorization also results in the outright denial of covered services, as evidenced by the Department of Health and Human Services Office of the Inspector General's (OIG) 2022 report.

To address the numerous inquiries and concerns, CMS has proposed several regulatory changes which ACP supports, including:

- prior authorization policies for coordinated care plans may only be used to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service is medically necessary;
- an approval granted through prior authorization processes be valid for the duration of the approved course of treatment and that plans provide a minimum 90-day transition period when an enrollee who is currently undergoing treatment switches to a new MA plan;
- MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in the TM statutes and regulations;
- MA plans cannot deny coverage of a Medicare covered item or service based on internal, proprietary, or external clinical criteria not found in TM coverage policies; and
- all MA plans establish a Utilization Management Committee ("Committee") to review all utilization management, including prior authorization, and ensure they are consistent with current TM national and local coverage decisions and guidelines.

While the College supports CMS' proposal to require MA organizations to establish a committee, we are concerned that the composition does not lend itself to protecting the integrity of the process. Specifically, the committee must include a majority of members who are practicing physicians, at least one of which is independent and free of conflict relative to the MA plan or organization and at least one other who is an expert regarding care of elderly or disabled individuals, and members representing various clinical specialties. ACP is concerned that only requiring *one* practicing physician who is independent and free of conflict relative to the MA plan or organization is far too few. Given that this committee is charged with ensuring prior authorization processes are being used appropriately, integrity and appropriateness must be safeguarded within the Committee itself. To help guard against the appearance of impropriety, the College recommends CMS revise the composition to put a greater degree of separation between the committee members and the MA plan or organization. We also recommend CMS include a requirement that when the committee reviews prior authorization policies applicable to an item or service, the review must be conducted with the participation of at least one committee member who has expertise in the use or medical need for that specific item or service. The College believes this requirement will help prevent waste and ensure beneficiaries' unobstructed access to medically necessary services.

Coupled with the Advancing Interoperability and Prior Authorization Processes (CMS-0057-P) proposed rule, ACP is confident that these changes will go far in modernizing what is now a manual, highly burdensome, imprecise, and costly process. Prior authorization is a challenging process for all involved and ACP strongly encourages CMS to leverage the health care community by helping facilitate conversations that lead to solutions. In conjunction with Medicine Forward, ACP has hosted two webinars addressing problems and workflow solutions to address the burdens of prior authorization, and we welcome the opportunity to inform CMS' ongoing work.

- Breaking Bad! Prior Authorization Harms the Physician-Patient Relationship (Recorded 5/31/2022)
- Breaking Bad Part II: ACP and Medicine Forward Advance Solutions for Prior Authorization (Recorded 10/3/2022)

Lastly, as emphasized at the outset, ACP urges CMS to work with congressional leaders to pass the Improving Seniors' Timely Access to Care Act, which was passed by the House of Representatives in 2022.

Protecting Beneficiaries and Increased Transparency: Marketing Requirements

ACP strongly supports CMS' proposal to increase the transparency of MA plans and their respective marketing policies. The College also supports the Agency's goal of ensuring that MA enrollees receive the same access to medically necessary care they would receive in TM. To that end, we believe the Agency's proposal to require agents to explain the effect of a beneficiary's enrollment choice on their current coverage whenever the beneficiary makes an enrollment decision is a great safeguard of TM and protection against current abusive marketing tactics. ACP also appreciates the Agency tightening MA marketing rules to protect beneficiaries from misleading advertisements and pressure campaigns. Prohibiting advertisements that do not mention a specific plan name and that use words, imagery, and logos in a confusing way is a critical step in ensuring information disseminated to beneficiaries is accurate and not misleading.

Due to the predatory nature and increasing role of third parties in the marketplace, ACP believes it is imperative that CMS addresses the increasing number of beneficiaries misled into believing an entity is the Federal Government or a product is endorsed by Medicare. While CMS is simultaneously building a health system to support health equity, trust in the Federal Government and the health system is of utmost importance. ACP greatly appreciates the Agency's recognition of this relationship and the impact that revising its own Medicare-related marketing requirements may have on fostering trust across all populations but particularly those most vulnerable. Therefore, we strongly believe that as enrollment in MA continues to grow and physicians and beneficiaries are presented with more opportunities to participate, maintaining open lines of communication with the physician and beneficiary population is essential to building strong relationships.

Since releasing our Promoting Transparency and Alignment in Medicare Advantage policy paper in 2017, ACP has sought to inform CMS' policymaking regarding MA. As we stated, MA organizations must be transparent in their processes, policies, and procedures for how they develop and administer their MA plans and portfolios. To ensure program integrity, MA organizations must also be transparent in how they (and other third parties) market their plans. CMS' proposal to prohibit the use of superlatives (e.g., "best" or "most") in marketing is a great start to protecting beneficiaries. Previously, CMS generally

required plans to provide substantiating data to support the use of a superlative only to the Agency. Currently, the beneficiary has no knowledge of how the superlative is determined, potentially misleading the beneficiary to believe a statement which may be partially or mostly true but lacking context and important specificity. ACP agrees that this is potentially misleading and supports the Agency prohibiting this practice unless the material provides documentation to support the statement, and the documentation is for the current or prior year, as proposed.

Strengthening Quality: Star Ratings Program

CMS is proposing several measure changes and methodological clarifications to MA and Part D Star Ratings. The College is highly supportive of CMS' proposal to establish a Health Equity Index (HEI) reward. ACP agrees that incentivizing MA and Part D plan participants to improve care to enrollees with social risk factors (i.e., dual eligible, low-income subsidies (LIS), and disability) has the potential to address social drivers of health. If finalized, the HEI reward would begin with the 2027 Star Ratings (2024 and 2025 measurement years). Proposals also include modification of the improvement measure hold harmless policy; removal of guardrails when determining measure specific thresholds for non-CAPHS (Consumer Assessment of Healthcare Providers and Systems) measures; and addition of a rule for sub-regulatory removal of Star Ratings measures when a non-CMS measure steward retires the measure. CMS is also proposing to remove the 60% exception for extreme and uncontrollable circumstances, but beginning with the 2024 Star Ratings, propose to replace the exception with a standard statistical method of removing extreme outliers instead. The College is encouraged by these proposed changes which have developed out of data-driven lessons learned throughout the PHE and promote alignment, equity, and patient-driven quality improvement in MA and Part D.

Advancing Health Equity

ACP commends CMS for continuing to revise regulations to improve health equity. Specifically, we strongly support the agency's proposal to expand the list of populations to include individuals: (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. As part of our ongoing commitment to being an anti-racist, diverse, equitable, and inclusive organization, the College supports efforts that advance health equity for all. Health inequities are the cumulative result of a biased system, and in challenging those systemic drivers, we strongly urge the Agency to work with the stakeholder community, including physicians and patients, to inform a holistic and intersectional approach to policymaking.

ACP additionally supports CMS' proposal to clarify the marginalized groups that MA plans must accommodate. Equity is a core strategic priority for the College. ACP firmly believes that all persons, without regard to where they live or work; their race and ethnicity; their sex or sexual orientation; their gender or gender identity; their age; their religion, culture, and beliefs; their national origin, immigration status, and language proficiency; their health literacy level and ability to access health information; their socioeconomic status; whether they are incarcerated; and whether they have an intellectual or physical disability must have equitable access to high-quality health care and must not be discriminated against based on such characteristics. These clarifications are essential to ensuring marginalized populations have sufficient access to care to ultimately achieve health equity.

As previously mentioned, nearly half (48%) of the eligible Medicare population are currently enrolled in a MA plan; the CBO predicts the number of enrollees to surpass those in TM by 2025. A fact that is often overlooked is that recent growth is largely attributed to the influx of and has been far greater for Black and Hispanic beneficiaries and those with low income compared with White beneficiaries and those with higher income. Using data from the Master Beneficiary Summary File from 2011 to 2019 (providing for over 524.4 million person-years), a recent study found that newly enrolled beneficiaries who selected MA were more likely to be Black individuals and dually eligible for Medicaid. The challenge, then, is determining the implications of greater heterogeneity in the program for enrollee outcomes. A recent review of 62 studies published since 2016 found few differences supported by strong evidence, but relatively few studies specifically examined population subgroups (e.g., beneficiaries from communities of color, living in rural areas, or dually eligible for Medicare and Medicaid). As MA continues to grow, ACP strongly recommends CMS, Congress, and others assess beneficiaries' experiences and the long-term sustainability of the Part A program and the solvency of the Part A trust fund.

Despite its challenges, the College appreciates CMS' recognition that Medicare must work toward a more equitable future and improving MA can help deliver better outcomes and added benefits at a lower cost. The Agency's proposal to expand the list of populations that MA must provide services to in a culturally component manner is an integral step. ACP is also supportive of the Agency's proposal to require MA organizations to develop and maintain procedures to offer digital health education to enrollees to improve access to medically necessary covered telehealth benefits. While CMS is proposing to provide a degree of discretion for MA organizations in the procedures developed and used to identify enrollees, and subsequent educational "designs," it is critical that this process is free from bias and there are no subsequent requirements (e.g., online portal enrollment) that could act as a barrier to accessing covered telehealth benefits.

A digital divide still exists in the United States and despite the promising potential of telemedicine in promoting health equity, numerous barriers to accessing these services persist, including limited access to the devices or internet services needed to engage in telemedicine, or limited skills and knowledge in how to use these services. This is especially true for the Medicare-eligible population. As part of meeting the cultural, informational, and linguistic needs of patients, the College believes that it must be a national priority to improve health literacy among those facing disparities in a culturally and linguistically sensitive manner and supports health literacy interventions to accomplish this. Ongoing training and support will be needed in many areas to promote digital literacy, and CMS' proposal is a positive first step in bridging that divide.

We also recommend that adequate funding be made available to develop effective communication mechanisms to address the needs of all patient populations in a manner that is understandable and culturally sensitive, as described in our 2022 paper, Reforming Physician Payments to Achieve Greater Equity and Value in Health Care. The College strongly supports the Agency's added intervention to provide culturally, and linguistically appropriate services. We also support CMS' proposal to specify that MA organizations, cost plans, and Part D sponsors must provide materials to enrollees on a standing basis in any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area or accessible format using auxiliary aids and services upon receiving a request for the materials or otherwise learning of the enrollee's preferred language and/or need for an accessible format using auxiliary aids and services. The College strongly believes that payers, physicians,

and other clinicians must make it a priority to meet the cultural, informational, and linguistic needs of patients, with support from policymakers and payers. As such, health care communications must be made in a language the patient understands, including the use of translation services needed in serving those with limited-English proficiency or who are deaf. CMS' proposal will have a meaningful impact in improving health literacy and increasing access to services for enrollees with limited-English proficiency or who are hard of hearing.

Part of improving health equity is also meeting the patient where they are. Whether a patient is a MA or TM beneficiary, desires and needs change over time and physicians practicing primary care are charged with capturing and acting on this information. Comprehensive management requires capturing the complete narrative of the patient, including social drivers that may be impacting their health. Currently, CMS does not permit MA plans to use the information from audio-only telehealth encounters to be scored for risk adjustment. For millions of MA beneficiaries, however, particularly patients in older groups and those who are Black, audio-only telehealth is the only safe and available option to receive care. Analysis shows this was due to various reasons, one of which was that many people within these demographics face technology-access barriers and a lack of digital health literacy. CMS' current risk-adjustment policy disadvantages communities already experiencing health disparities. This policy also results in: an underestimation of the total cost of care; reduced benefits; increased out-of-pocket costs; reductions in payments; and an incomplete record that fails to capture social drivers of health and the complete picture of the patient. To protect beneficiaries who rely on their MA plans for comprehensive coverage, ACP recommends, as clinically appropriate, CMS allow diagnoses from MA audio-only telehealth encounters to be included in risk adjustment calculations, consistent with CMS' treatment of risk adjustment across other Federal programs. As CMS considers the future status of audio-only telehealth visits, we also strongly urge the agency to ensure reimbursement is appropriate and supports utilization of and access to this critical service.

As CMS works towards implementing these revisions, we recommend that physicians and representatives from their vulnerable patient populations be engaged to inform these efforts.

Improving Access to Behavioral Health

ACP applauds CMS for paying particular attention to access gaps in behavioral health services. Cultivating effective and sustainable integration of behavioral and mental health care into primary care practices has been a focal point of the College's as the nation weathers a mental health and substance abuse crisis. Through our behavioral health integration efforts, we have emphasized the importance of ensuring adequate access to and reimbursement for behavioral health services and the need to expand network adequacy. We support CMS' proposals to strengthen these network adequacy requirements and reaffirm MA organizations' responsibility to provide behavioral health services.

Additionally, the College commends CMS for acting to close equity gaps in treatment between physical health and behavioral health. We appreciate CMS extending current requirements for MA organizations to establish care coordination programs, including coordination of community, social, and behavioral health services. Extension of these requirements will help move behavioral health towards parity and advance whole-person care. The College is also confident that the addition of clinical psychologists, licensed clinical social workers, and prescribers of medication for opioid use disorder to the list of evaluated specialties under MA will help ensure MA beneficiaries have access to "providers" that specialize in behavioral health services.

Improving Drug Affordability and Access in Part D

CMS proposes to permit Part D sponsors to immediately remove from its formulary and substitute: (1) a new interchangeable biological product for its corresponding reference product; (2) a new unbranded biological product for its corresponding brand name biological product; and (3) a new authorized generic for its corresponding brand name equivalent without having to give beneficiaries advance notice or providing a transition supply of the removed drug.

ACP supports CMS' proposal to allow for the removal and substitution of certain prescription drugs from Part D formularies in limited circumstances. Given the role of prescription drugs as an important tool for managing and treating serious health issues, the College is extremely concerned about the impact that rising prescription drug prices have on patient access and medication adherence. To counteract rising prescription drug spending, ACP supports efforts by Medicare Part D to promote the use of generic prescription drugs and biosimilars, provided therapeutic safety and equivalency are established. CMS' proposal has potential to constrain prescription drug spending while promoting maximal patient access to critical, life-saving treatments.

Additionally, ACP is encouraged by CMS proposing changes to the Medication Therapy Management (MTM) eligibility criteria including: requiring Part D sponsors to include all core chronic diseases in their targeting criteria; codifying the current 9 core chronic diseases in regulation; addition of HIV/AIDS as a core chronic disease; and revising the cost threshold methodology. These proposed changes support the College and CMS' aligned commitment to expanding prescription drug access and affordability.

Implementation of Certain Provisions of the Consolidated Appropriations Act (CAA), 2021 and the Inflation Reduction Act (IRA)

Making Permanent: Limited Income Newly Eligible Transition (LI NET) Program

CMS proposes making the LI NET Program a permanent program within Medicare as required by Section 118 of Division CC, Title I, Subtitle B of the CAA. LI NET "provides transitional, point-of-sale coverage for low-income beneficiaries who demonstrate an immediate need for prescriptions, but who have not yet enrolled in a Part D plan, or whose enrollment is not yet effective. LI NET also provides retroactive and/or temporary prospective coverage for beneficiaries determined to be eligible for the Part D LIS by the Social Security Administration or a State."

ACP supports CMS' proposal to make the LI NET Program a permanent program. The College has long believed that the highest priority should go toward providing prescription drug benefits for those most in need: low-income beneficiaries who do not have access to drug coverage under other plans. Making the LI NET Program permanent is critical to ensuring that those transitioning between the Medicaid and Medicare programs can maintain important prescription drug regimens and do not experience a gap in prescription drug coverage.

Enhancing Financial Stability: Expanding Low-Income Subsidies Under Part D

CMS proposes to expand eligibility to the full Part D LIS to those making up to 150% of the federal poverty level, as well as allowing individuals to qualify for the full subsidy based on the higher resource requirements currently applicable to the partial LIS group, as required by Section 11404 of the IRA.

ACP supports CMS' proposal to expand eligibility to the full Part D LIS. The College has long expressed concern over the rising cost of prescription drugs, particularly for low-income patients as they struggle to afford basic and life-saving medications prescribed by their physicians to treat diseases and chronic conditions. ACP believes that providing prescription drug coverage to low-income Medicare beneficiaries should be of the highest priority. Thus, ACP supports the funding and expansion of programs to assist low-income Medicare beneficiaries in paying their Part D costs, such as the LIS. Expanding full LIS eligibility and altering the resource requirements applicable for qualification is a vital step in increasing access to prescription drugs and promoting treatment adherence.

Conclusion

ACP greatly appreciates the opportunity to share our perspective and provide requested information on advancing health equity, accessing health care and related challenges to delivery, and understanding physician and beneficiary experiences with various CMS programs. The College continues to welcome partnership with CMS and Congress to revise regulatory policies and inform future rulemaking and legislation.

Sincerely,

William Fox, MD, FACP
Chair, Medical Practice and Quality Committee
American College of Physicians