March 7, 2022

Chiquita Brooks-LaSure
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 (CY) 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192-P)

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 revisions to the Medicare Advantage (MA) (Part C) program and Medicare Prescription Drug Benefit (Part D) program regulations. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 161,000 internal medicine physicians (internists), 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 adjust across the spectrum from health to complex illness.

ACP was very pleased with CMS' proposals to revise the MA and Part D regulations. The College's detailed comments on specific proposals can be found below.

Beneficiary Cost-Sharing Adjustments
CMS Proposal: There has been an increased occurrence of Part D plans entering into a type of arrangement with pharmacies that may pay less for dispensed drugs if the pharmacies fail to meet certain criteria set by the plans. Due to the uptick in these arrangements and the process by which the negotiated price is determined, the negotiated price is now frequently higher than the payment pharmacies receive. When the negotiated price increases, so does the cost to the patient. CMS has proposed a redefined negotiated price beginning January 1, 2023. This would require Part D plans to apply all savings they receive from network pharmacies to the point of sale, so that the patient can also share in the savings.

ACP Comments: The College is pleased by CMS' effort to solve this issue through increasing transparency and requiring savings to be shared with patients, reducing out-of-pocket costs. ACP has long been supportive of lowering drug prices and believes health plans, PBMs, and pharmaceutical manufacturers should engage in higher levels of transparency such as increased reporting on the amount paid for prescription drugs, aggregate number of rebates, and non-proprietary pricing information to the Department of Health and Human Services should be made publicly available. ACP strongly believes that the health system prioritizes the need to put patients first. This proposal could act

as a powerful onramp to increasing transparency and reducing costs throughout the system. In January of this year, ACP signed on to a joint letter supporting proposals to eliminate the patient cost-sharing associated with chronic care management across public and private insurance. Furthermore, ACP encourages CMS to support additional modification to the Medicare Part D low-income subsidy (LIS) program cost-sharing and copayment structures to encourage the use of lower-cost generic or biosimilar drugs, such as eliminating cost-sharing for generic drugs.

Marketing and Communications Oversight

CMS Proposal: CMS proposed several changes to marketing and communication requirements which emphasize the importance of providing Medicare beneficiaries with accurate and accessible information. A part of that effort is realized through CMS' proposal to require MA and Part D plans create a multi-language insert (includes the top 15 languages used in the U.S.) which would inform the reader that interpreter services are available for free. The multi-language insert would be required to be included whenever a Medicare beneficiary is provided with CMS required material such as evidence of coverage, annual notice, summary of benefits, etc. CMS also proposed changes impacting oversight of third-party marketing organizations to reduce deceptive marketing tactics used to enroll beneficiaries in MA and Part D plans.

ACP Comments: ACP is supportive of CMS' proposal to require MA and Part D Plans to create a multi-language insert to inform patients that interpreter services are available for free. In February 2022, ACP presented a statement for the record before the Senate Ways and Means Committee which highlighted that individuals with "intellectual or physical disability must have equitable access to high-quality health care and must not be discriminated against based on such characteristics." Removing the language barrier to receive appropriately accommodated resources is an important element of equality for patients with disabilities. ACP is also pleased that CMS is proposing increased oversight for prescription drug marketing tactics. While we do not have explicit policy on this issue, we believe that decision about one's treatment plan should first and foremost be between the doctor and their patient.

Plan Request Denials

CMS Proposal: CMS' proposed rule would expand the list of reasons for which CMS can deny a new contract for a MA plan or Part D sponsor to include having a Star Rating of 2.5 or lower, filing for bankruptcy, and having a number of compliance actions which exceeds a threshold to be established by the Agency.

ACP Comments: The College believes that CMS' ability to ensure poor performers are not allowed to enter into or expand in MA is important to protecting both physicians and patients. In the limited context of bankruptcy, a proposed new bases for denial, this could result in the closure of an organization's operations, thereby restricting the physician's ability to provide health care services to beneficiaries in a high-quality manner. Due to the possible negative impact to physicians and patients, ACP believes **the proposed new bases for denying a new contract or service area expansion of an existing contract based on past performance is a welcome change as it serves to hold MA plans to a higher standard.**

Medical Loss Ratio (MLR) Reporting

CMS Proposal: Since 2014, all Medicare Advantage organizations (MAOs) and Part D sponsors have been required to submit their medical loss ratio (MLR) data to CMS. The MLR represents the percentage of the plan's revenue used for patient care rather than administrative costs or profit. MA plans are subject to financial or other penalties if they do not reach an MLR of at least 85% and the detailed reports of expenditures seek to validate compliance. In 2018, consistent with the prior Administration's Executive

Order on alleviating regulatory burdens, the Agency significantly reduced the amount of MLR data that plans are required to submit. In the CY23 proposed rule, CMS has proposed to reinstate the MLR reporting standards that were in effect from 2014-2017. This would effectively require MA and Part D plans to report underlying costs and revenue information necessary for verifying the reported MLR and the amount of any remittance owed for failure to meet the minimum MLR 85%. CMS has also proposed to resume publicly releasing the more detailed MLR data.

ACP Comments: ACP is greatly supportive of the Agency's proposed reinstatement of the MLR reporting requirements. As a result of the previous Administration's initiative to reduce regulatory burdens, CMS and the public had less insight into MAO and Part D sponsor MLR compliance outside of audits. **The College believes that reinstating these requirements and publicly releasing the MLR data will help to both improve market transparency, as well as beneficiary choice.** In restoring the Agency's reporting policy, we additionally hope these clinical or quality standards will be more clearly defined, objectively measurable, and well-documented as to support physician incentives and permit for more precise documentation around quality improvement activities.

Special Needs Plans (SNPs)

CMS Proposal: CMS has also proposed a number of changes for SNPs that serve Medicare-Medicaid dual eligible (D-SNPs) and beneficiaries with chronic conditions:

- SNPs for D-SNPs would be required to form an enrollee advisory committee.
- As part of Health Risk Assessments (HRAs) conducted by SNPs, all HRAs would be required to include one or more specific standardized questions on housing stability, food security, and access to transportation. This would better identify and enable MA and SNPs to address risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes.
- Beginning in 2024, a SNP that is a fully integrated dual-eligible special needs plan (FIDE SNP) would need to have exclusively aligned enrollment for Medicaid purposes and cover Medicaid home health, durable medical equipment, and behavioral health services through a capitated contract with the state Medicaid agency.
- Codification of new pathways for states to use their contracts with D-SNPs to better integrate care for dually eligible individuals.
- Plans would have to calculate a beneficiary's maximum out-of-pocket spending based on the accrual of all cost-sharing in the plan benefit, regardless of whether that cost-sharing is paid by the beneficiary, Medicaid, or other secondary insurance.

ACP Comments: The College is very pleased with CMS' proposals to offer fully integrated Medicare and Medicaid services to enrollees. Currently, about 3.7 million dually eligible beneficiaries receive their Medicare services through D-SNPs. **These proposed changes related to D-SNP beneficiaries will be extremely important in addressing the barriers to care coordination in D-SNP beneficiary populations.** ACP additionally believes CMS' proposed policy that the "representative sample", that will inform the advisory committee, will be a valuable beneficiary protection to ensure enrollee feedback is heard and will support identification of barriers to high-quality, coordinate care. The College also appreciates CMS' intent to incorporate multiple characteristics of the total enrollee population of the D-SNPs served by the enrollee committee, including but not limited to geography, service area, and demographic characteristics. To adequately assess and provide for high-quality care, it is critical that enrollees are engaged in defining, designing, and participating in these care systems. In creating these proposed enrollee advisory committees, the College urges CMS to ensure that meetings are accessible to all enrollees, including but not limited to enrollees with disabilities, limited literacy (including limited digital literacy), and lack of meaningful access to technology and broadband.

While ACP is supportive of CMS' proposal to include specific questions addressing social drivers of health (SDOH) in the HRAs, we remain concerned that permitting a one question minimum will not prove fruitful in fulfilling the Agency's intent. The College encourages the Agency to provide more detail into the level of discretion that entities may have in determining whether one or several of these questions will be included in the HRAs, as well as what factors may play into determining which question(s) to include. The awareness of SDOH information improves the whole person, patient-centric care and lowers long-term costs. Since an individual's health is impacted by the sum of these various social needs, having the most complete, comprehensive information about an individual is critical to delivering the best care. **In including these SDOH-related questions in the HRAs, however, the College strongly urges CMS to provide adequate protection for and confidentiality of this information.** These increased protections have long been supported by ACP. SDOH-related information is a fundamental aspect of providing high quality care, but the collection and use of this information should be held to the highest standard and appropriate oversight and enforcement should restrict inappropriate use and assess.

To successfully promote standardization of this SDOH-related information, ACP encourages CMS to publish sub-regulatory guidance providing the exact language of these questions. The College supports the Agency's intent to align selected questions with the SDOH Assessment data element established as part of the USCDI v2. **However, there is still clarification needed to make certain the USCDI v2 questions would integrate seamlessly with traditional health information and result in successful interoperability.** For these reasons, ACP hopes this sub-regulatory guidance additionally provides details on how this proposal would be made implementable in practice. In order to equip MAOs with the requisite individual-level information that would help them better connect individuals to covered services, social service organizations, and public programs, it is essential that this information be collected in a manner to make most effective the facilitation of better data exchange among SNPs. **As the Agency considers public comments and begins finalizing the included proposals, ACP welcomes the opportunity to work with CMS to better inform the implementation process.** The College remains committed to achieving health equity and the MA program is a great pathway to attaining the highest level of health for the individual, despite any factors that affect health outcomes.

Conclusion

ACP appreciates the opportunity to provide feedback to CMS on the proposed rulemaking regarding revisions to the MA (Part C) program and Medicare Prescription Drug Benefit (Part D) program regulations. The College is encouraged that the Agency has reinstated the regulatory protections for physicians and beneficiaries to benefit from improved patient care and outcomes, as well as reduce health care costs for out-of-pocket costs for prescription drugs under Part D. We look forward to continuing to work with CMS on addressing these important issues and thank you for considering our comments. Please contact Brian Outland, Director, Regulatory Affairs for the American College of Physicians, at boutland@acponline.org or (202) 261-4544 with comments or questions about the content of this letter.

Sincerely,

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