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March 7, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4192-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS–4192–P; Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

Dear Administrator Brooks-LaSure,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs proposed rule, which was published in the Federal Register on January 12, 2022.

ASCO is a national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

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Health Equity

Consistent with the Biden administration's focus on enhancing health equity and beneficiary protections, the proposed rule contains several proposals aimed at streamlining and simplifying dual-eligible special needs plan (D-SNP) offerings, improving beneficiary engagement, and addressing health equity. ASCO applauds the efforts the agency has made to address and enhance health equity through proposals in this rule.

Enrollee Participation in Plan Governance

Building on experience with other programs, such as the Medicare-Medicaid Financial Alignment Initiative (FAI) and Programs of All-Inclusive Care for the Elderly (PACE), CMS proposes to require Medicare Advantage Organizations (MAOs) offering one or more D-SNPs in a state to establish and maintain one or more enrollee advisory committees to solicit direct input on ways to improve access to covered services, coordination of services, and health equity.

ASCO supports CMS' proposal to require MAOs offering one or more D-SNPs to establish and maintain enrollee advisory committees to solicit direct input on ways to improve access to covered services, coordination of services, and health equity.

As demonstrated in FAI and PACE programs, enrollee advisory programs provide MAOs with valuable and insightful enrollee perspectives leading to enhanced quality and plan design. Enrollee advisory committees in FAI programs have helped shape the plan's approach to improve access to health care and have identified and prioritized areas where additional assistance is needed for enrollees. PACE organizations value the participant advisory committees as they receive direct feedback from PACE participants to improve program policy and operations. These two programs have demonstrated that the use of advisory committees improves plans' ability to meet their enrollees' needs by providing plans with a deeper understanding of the communities the plans serve and the challenges and barriers their enrollees face. Dual-eligible enrollees should have equal opportunity to play an integral role in plan design, enabling D-SNPs to meet the unique health care needs of those they serve.

Opportunities such as the establishment of advisory committees can provide critical openings for enrollees and plans to examine, discuss, and consider solutions affecting cancer health equity. As data have illustrated, while cancer is a disease that can affect anyone, it does not affect everyone equally. African Americans and other racial and ethnic groups, those with low incomes, those living in low-quality housing and unsafe environments, and people in rural areas often face greater obstacles for cancer screening, diagnosis, and treatment.[1] Sexual and gender minority populations bear a disproportionate cancer burden. The disparities in cancer outcomes stem from the unique cancer risks, needs, and challenges faced by this population including discrimination and gaps in quality of care.[2,3] Integration of the enrollee voice, perspective, and needs into plan design can enhance the quality of D-SNPs and aid in prioritizing the needs of dual-eligible enrollees and these other populations at higher risk for experiencing disparities in care. Effective implementation of advisory committees, when the resulting

[1] *Cancer Disparities*. National Cancer Institute (NCI). https://www.cancer.gov/about-cancer/understanding/disparities#:~:text=Cancer%20health%20disparities%20happen%20when,ethnicities%2C%20or%20other%20population%20groups. Accessed 28 Feb. 2022.
[2] Graham, R., Berkowitz, B., Blum, R., Bockting, W., Bradford, J., de Vries, B., & Makadon, H. (2011). The health of lesbian, gay, bisexual, and transgender people: Building a foundation for better understanding. *Washington, DC: Institute of Medicine*.
[3] Gibson, A. W., Radix, A. E., Maingi, S., & Patel, S. (2017). Cancer care in lesbian, gay, bisexual, transgender and queer populations. *Future Oncology*, 13(15), 1333-1344.

policies and procedures are responsive to enrollee input, will aid in identifying, addressing, and easing barriers to high-quality and equitable cancer care for dually eligible individuals.

ASCO supports CMS' proposal to require MAOs to establish and maintain D-SNP enrollee advisory committees. We support the requirement that advisory committees must be geographically and demographically representative of each D-SNP enrollee population. ASCO supports policies such as this that promote collaboration between patients, providers, and other stakeholders in the health care system to improve access to high-quality and equitable cancer care.

Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessment

Under current statute and regulation, special needs plans (SNPs) are required to conduct an initial assessment and an annual reassessment of each enrollee's physical, psychosocial, and functional needs. This rule proposes that all SNPs and D-SNPs incorporate standardized questions on the topics of housing stability, food security and access to transportation as part of the health risk assessment (HRA). SNPs would not be accountable for resolving all the risks identified but CMS notes that current regulations require that the results of the HRAs be addressed in the individual's care plan, which could include, for example, making an appropriate referral to a community resource.

ASCO supports CMS' proposal to require initial and annual health assessments to include standardized questions on enrollees' social determinants of health.

ASCO supports policies and practices that address the social determinants of health. Achieving cancer health equity requires broad approaches that address the social, economic, and environmental factors that influence health; addressing the social determinants of health is critical to achieving health equity. Additionally, multisector collaborations can help promote and sustain health equity, and enrollees, plans, and health care systems should leverage community resources to improve health equity.

Following an HRA, SNPs would need to consult with enrollees about their unmet social needs in developing each enrollee's care plan. This conversation invites professional and community partnerships to collaborate and support enrollees in achieving their health care needs by addressing the barriers they face in accessing care. Identifying strategies to address social determinants of health in this manner will promote and sustain the policies and implementation activities that are crucial to reducing health disparities.

ASCO recognizes that patient data are often incomplete, inaccurate, or overly simplified and usually do not consider many social and community factors.[4] There is a lack of comprehensive, consistent data on factors that impact disparities in cancer care and patient outcomes, including patients' social status and demographics and community and lifestyle factors. ASCO agrees with CMS that having standardized data on enrollees' social determinants of health could aid in better understanding the prevalence and

[4] Polite, Blase N., et al. "Charting the future of cancer health disparities research: a position statement from the American Association for Cancer Research, the American Cancer Society, the American Society of Clinical Oncology, and the National Cancer Institute." Cancer research 77.17 (2017): 4548-4555.

trends in certain social risk factors across SNPs. Analysis of standardized data can lead to consideration of ways to support SNPs in promoting better outcomes for their enrollees.

ASCO is pleased that CMS has placed an emphasis on addressing SDOH across all programs in its continued efforts to move toward a value-based model of care delivery. ASCO urges CMS to establish consistent measures across its various programs to reduce reporting burden and to enhance robustness of the data collected.

Attainment of the Maximum Out-of-Pocket (MOOP) Limit

MAOs are required to establish an annual limit on beneficiary out-of-pocket costs for Medicare Part A and B services. After that limit, the MAO must pay 100% of the service costs. Under current guidance, MAOs do not have to count Medicaid-paid amounts or unpaid amounts toward this limit. CMS believes that this approach disadvantages providers serving dual eligible individuals in Medicare Advantage (MA) plans and proposes that the MOOP limit in an MA plan be calculated 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 or remains unpaid because of state limits.

ASCO supports CMS' proposal to specify that the MOOP limit in a D-SNP plan is based on all cost-sharing paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid.

We agree with CMS that this proposal has the potential to mitigate existing provider payment disincentives related to serving dually eligible MA enrollees and that finalization of this proposal may improve dual-eligible enrollees' access to oncology providers. Additionally, determination of claims alone, regardless of the enrollee's dual eligibility status, could bring consistency to how MA organizations determine if the MOOP limit has been attained. This is especially important as variations in MOOP calculations occur across various plans making financial planning difficult for providers. ASCO strongly supports this proposal as a means to maintain a robust oncology provider population available to care for those enrolled in D-SNPs.

Pharmacy Price Concessions in the Negotiated Price

Under current regulations the term "negotiated price" is defined as the total amount a pharmacy and a plan have negotiated as the payment amount for a drug, excluding fees that cannot reasonably be determined at the point of sale. As contracts become increasingly based on pharmacy performance, many pharmacy payment arrangements now commonly involve retrospective reconciliation after the end of a calendar year or other period, commonly referred to as "claw backs." One such example is quality incentive payments to a pharmacy based on achievement of certain quality metrics or additional price concessions that the pharmacy may pay to the plan.

CMS proposes to redefine the term "negotiated price" to mean the "lowest possible reimbursement" a pharmacy might receive, in total, for a particular drug. Under the proposed definition, the negotiated price would include all dispensing fees and all price concessions that might possibly be paid in the future

by a pharmacy to a plan, including performance penalties. Including pharmacy price concessions at the point of sale, instead of reporting as direct or indirect remuneration (DIR) at the end of the plan year, reduces the cost of the drug at the point of sale. Because beneficiary cost sharing is determined at the point of sale based on the negotiated price, including these price concessions at the point of sale will subsequently reduce beneficiary cost sharing.

ASCO supports the updated definition of "negotiated price" to include performance penalties at the point of sale; however, we are concerned about the widespread practice of PBM application of Star performance ratings and related DIR claw backs on oncology dispensing physicians and practice-based pharmacies.

Even for patients with insurance, out-of-pocket expenses associated with cancer treatment may be substantial and lead to exhaustion of savings and personal ("medical") bankruptcy. Moreover, these expenses have a disproportionate effect on those with lower incomes. Cancer patients should not be further penalized for the financial struggles they must endure when diagnosed with cancer by allowing PBMs and plan sponsors to report pharmacy price concessions as DIR instead of at the point of sale, which results in increased cost sharing and greater financial burden for patients. To promote access to life-saving and supportive care treatment and to promote reduced financial burden for vulnerable patients, CMS should finalize the proposed definition of "negotiated price."

While we support CMS' proposal to redefine the term negotiated price, thereby reducing beneficiary cost sharing at the point of sale, we strongly disagree with PBM application of CMS' Star Rating System to unfairly and unjustifiably penalize oncology practices and practice-based pharmacies.

PBMs justify imposition of these performance-based DIR fees by referencing CMS' Star Rating System. The Star Rating System is used by CMS in Medicare Advantage and Medicare Part D to measure performance on plans covering drug services. The Star Rating System measures relate largely to medication adherence for conditions such as diabetes, hypertension, and cholesterol; and was designed to apply to Part D plan sponsors, not pharmacies. No such measures exist for medication management in oncology.[5]

Despite the lack of oncology measures and the misapplication of these fees on pharmacies instead of plan sponsors, these fees are nevertheless charged directly to oncology pharmacy providers, who assert this is done in a way that that lacks transparency and is highly profitable for PBMs. These performance-based fees are not required by HHS or CMS regulations and appear to have no basis in statute.[6]

[5] https://www.cms.gov/files/document/2022-star-ratings-fact-sheet1082021.pdf
[6] PBM DIR Fees Costing. Medicare and Beneficiaries: Investigative White Paper on. Background, Cost Impact, and. Legal Issues. Prepared by. Frier Levitt, LLC. Commissioned by the Community Oncology Alliance. January 2017.

Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application

MAOs must maintain provider networks that meet specific time and distance criteria established by CMS. To strengthen its application standards and oversight, CMS is proposing to require that plan applicants demonstrate they have a sufficient network of contracted providers to care for beneficiaries before CMS will approve an application for a new or expanded MA plan.

ASCO supports CMS' proposal to require plans that are applying for new or expanded service areas to demonstrate they meet MA network adequacy standards as part of the application process.

Cancer patients and survivors are a particularly vulnerable subset of the population. They require timely access to cancer specialists, facilities, and supportive care. Narrowed networks[7,8] are linked to delays in cancer care, delays that adversely affect cancer control and survival.[9] To ensure that cancer patients have immediate access to the necessary anti-cancer therapies, we support this proposal

Our membership includes oncology practices in every state and across a wide range of settings, including urban, rural, and underserved areas. ASCO supports network adequacy standards and policies that promote access based on specific patient needs, availability of care and providers, and appropriate utilization of services. We believe this proposal will assure cancer patients and survivors have meaningful access to medically necessary cancer care services in a timely fashion.

Request for Information: Prior Authorization for Hospital Transfers to Post-Acute Care Settings during a Public Health Emergency

CMS seeks general feedback on how MAOs' prior authorization requirements for patient transfers impact a hospital's ability to furnish the appropriate care to patients in a timely manner during the public health emergency (PHE). ASCO would like to highlight that prior authorization has a far greater impact on patients and providers beyond what is occurring in hospitals when transfer to post-acute services is delayed. We urge the agency to assess the impact of MAOs' prior authorization requirements on physicians' ability to effectively manage resources and provide appropriate and timely care both during the PHE and beyond.

The agency indicated in the proposed rule that the primary objective of the RFI was to "glean information … about the effects of MAO's PA requirements…" Prior authorization programs are having a detrimental impact on oncology care. Prior authorization can lead to delays in in starting physician-recommended treatment leading to detrimental outcomes for cancer patients; treatment changes or

[7] Wharam JF, Zhang F, Lu CY, et al: Breast cancer diagnosis and treatment after high-deductible insurance enrollment. J Clin Oncol 36:1121-1127, 2018
[8] Wharam JF, Zhang F, Wallace J, et al: Vulnerable and less vulnerable women in high-deductible health plans experienced delayed breast cancer care. Health Aff (Millwood) 38:408-415, 2019
[9] Eriksson L, Bergh J, Humphreys K, et al: Time from breast cancer diagnosis to therapeutic surgery and breast cancer prognosis: A population-based cohort study. Int J Cancer 143:1093-1104, 2018

abandonment; unexpected out of pocket costs; and rejection of physician-recommended treatment. In addition to this impact on patient care, prior authorization contributes to unnecessary administrative burden on physicians.

ASCO refers CMS to its 2017 policy statement[10] on utilization management in which we recommend an appropriate framework for the design of utilization management programs. We remain committed to the principles and recommendations conveyed in this document, and to working with stakeholder groups to develop and implement policies that benefit patients with cancer while reducing unnecessary or wasteful costs. We urge CMS to incorporate the principles of the statement as it works to develop streamlined, transparent, and evidence-based policies that support appropriate utilization of healthcare services. We set forth six critical principles that any utilization management policy must meet to ensure medically necessary care for patients with cancer is not jeopardized or unreasonably delayed:

- Individuals with cancer should have full access to the anti-cancer therapy most appropriate for their disease when used in accordance with current clinical and scientific evidence.
- Cost should not be the primary driver of utilization management policies.
- Utilization management policies should be evidence-based and reflect the most current science and understanding of cancer treatment.
- Utilization management processes should result in timely and clear determinations that are consistent with the health insurer's coverage and other policies.
- Payer cost containment strategies and decision-making processes should be transparent and without conflicts of interest.
- Payers should implement utilization management policies in a way that minimizes administrative burdens–specifically time and effort–on both providers and patients.

ASCO is committed to supporting policies that reduce cost while preserving or increasing quality of cancer care, but we believe that utilization management tools such as prior authorization should be implemented in a transparent and evidence-based manner and in a way that does not undermine patient access to medically necessary care.

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We appreciate the opportunity to comment on the 2023 Medicare Advantage and Part D proposed rule. Please contact Gina Hoxie (gina.baxter@asco.org) with any questions or for further information.

[10] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-UM-Update.pdf

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Sincerely,

Howard A. Burris III, MD, FACP, FASCO

Chair of the Board

Association for Clinical Oncology