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December 20, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20001

Submitted Electronically at www.regulations.gov

Re: 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 (CMS–4205–P)

Dear Administrator Brooks-LaSure,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the 2025 Medicare Advantage and Part D proposed rule (CMS–4205–P) that was issued in the Federal Register on November 6, 2023.

ASCO is a national organization representing nearly 50,000 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.

We are pleased to offer our comments on select provisions below.

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Annual Health Equity Analysis of Utilization Management Policies and Procedures

CMS is proposing to require Medicare Advantage health plans to analyze their prior authorization and other utilization management (UM) protocols from a health equity perspective. CMS is proposing to require that a member of the

UM committee have expertise in health equity, to require the UM committee to conduct an annual health equity analysis of prior authorization policies and procedures used by the Medicare Advantage plan organization, and to require Medicare Advantage plan organizations to make the results of the analysis publicly available on their website. The goal of the health equity analysis is to create additional transparency and identify disproportionate impacts of UM policies and procedures on enrollees who receive the Part D low-income subsidy, are dually eligible, or have a disability. **ASCO strongly supports this proposal, and we make several recommendations below to enhance what has been proposed.**

Mounting evidence indicates that prior authorization requirements may be discriminatory and worsen health disparities. Additionally, individuals who face challenges accessing and paying for care may not be aware of how the prior authorization process works, or how it may disadvantage them. To protect against further exacerbating current health disparities, the need for a more transparent, efficient prior authorization process is critical—especially for smaller, under-resourced providers and patient populations.

UM Committee

CMS is proposing to require the UM committee to have at least one member with expertise in health equity. CMS is proposing that health equity expertise includes educational degrees or credentials with an emphasis on health equity, experience conducting studies identifying disparities amongst different population groups, experience leading organization-wide policies, programs, or services to achieve health equity, or experience leading advocacy efforts to achieve health equity. **ASCO supports this proposal and urges CMS to finalize implementation.**

Health Equity Analysis

CMS is proposing to require the UM committee to conduct an annual health equity analysis of prior authorization policies and procedures used by the Medicare Advantage plan organization and to make the results of the analysis publicly available on their website. The goal of the health equity analysis is to create additional transparency and identify disproportionate impacts of UM policies and procedures on enrollees who receive the Part D low-income subsidy, are dually eligible, or have a disability. **ASCO supports CMS' proposal to require this analysis be done at the plan level, and we support the proposed metrics to be included in the analysis. ASCO does not believe that results are meaningful when aggregated; therefore, we strongly urge the Agency to require analysis be done at the service level.**

While we strongly support transparency and the metrics outlined in the proposed rule, we believe that aggregating this data across all items and services may fail to provide meaningful and actionable information for specific specialties, patients undergoing complex treatments, and even for CMS. A better approach would be for the plan to provide specific data points related to certain specialties, like oncology treatment. Without more granular information, we are concerned that the data will be too broad to show how often specific treatments and services are impacted by payer policies and CMS will

be unable to effectively monitor the adverse impact of plan prior authorization policies, including suboptimal clinical outcomes, increases in adverse events and disparities in treatments.

Any patient or provider, as well as all other interested parties, should have meaningful access to prior authorization information metrics, including whether prior authorization is required, and if so, the number of times the request for a particular services or drug has been denied, approved, or approved after appeal. The information should be available immediately at the most granular level at an individual's request, though not necessarily posted. An individual should be able to query a search function and return the information they are looking for at the level of aggregation they request.

Finally, we support CMS' proposal to obtain from Medicare Advantage plans and to publish on the CMS website all of the prior authorization data that Medicare Advantage plans are required to make public, including, but not limited to, prior authorization equity analysis data. Publishing this data on a single governmental website will facilitate public access and enable Medicare beneficiaries, providers, and researchers to easily compare Medicare Advantage plans' prior authorization practices.

Additional Patient Populations

ASCO strongly believes that CMS should also include in the health equity analysis: members of racial and ethnic communities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; and members of rural communities.

Inequalities endure within and across multiple cancer diagnoses and population groups. Variations in cancer outcomes continue to be associated with factors such as race/ethnicity, sexual orientation and gender identity, age, geography (e.g., rural v. urban), socioeconomic status, and health literacy, among many others.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 populations including discrimination and gaps in quality of care.^{2,3} To prevent further inequities, stakeholders and patients that make up these populations need to understand the impact of prior authorization on cancer care. Individuals that make up these populations should be able to access information in a meaningful way to help them make informed decisions about their coverage.

ASCO strongly urges CMS to monitor and remedy the predictable, adverse consequences that individuals with cancer may experience from barriers or delays in receiving preferred oncology therapies because of prior authorization requirements, including suboptimal clinical outcomes, increases in adverse events, increases in emergency department visits, and disparities in treatment or outcomes. For more

¹ NCI: Understanding Cancer Disparities, 2018. <https://www.cancer.gov/about-cancer/understanding/disparities>

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.

information, please see our affiliate, The American Society of Clinical Oncology’s Position Statement on Prior Authorization found [here](#).⁴

Additional Changes to an Approved Formulary— Biosimilar Biological Product Maintenance Changes and Timing of Substitutions

In the 2024 Medicare Advantage/Part D proposed rule, ASCO opposed CMS’ proposal to allow Part D sponsors to make immediate formulary changes by substituting a new interchangeable biological product for its corresponding reference product without advanced beneficiary notification. ASCO was concerned that Part D plan sponsors could provide notice of these specific changes, including direct notice to affected beneficiaries, after formulary substitutions take place and would not need to provide a transition supply of the substituted drug. We reiterate our opposition to this proposal again this year.

In this proposed rule for 2025, CMS is proposing to permit Part D plan sponsors to treat formulary substitutions of biosimilar biological products other than interchangeable biological products for their reference products as “maintenance changes” that would not require prior approval by CMS. Currently, plans must obtain explicit approval from CMS prior to substituting a reference product with biosimilar biological products other than interchangeable biological products. Treating these substitutions as maintenance changes would mean that any substitutions would apply to all enrollees (including those already taking the reference product prior to the effective date of the change) following a 30-day notice.

ASCO supports the proposed flexibility and the efforts to enhance biosimilar use by Medicare beneficiaries in both the 2024 and 2025 proposals; however, we strongly believe that substitution of a patient’s drug therapy, regardless of an “interchangeable” designation, needs to be determined between the patient and the physician and that 30 days is insufficient to fully analyze and implement that change. Additionally, we do not support the distinction between “interchangeable” and “biosimilar biological products other than interchangeable”. We urge CMS to finalize policy that would allow payers to add “interchangeable” and “biosimilar biological products other than interchangeable” to formularies mid-year without removing the reference product during that plan year. Payers should ensure that changes to prescribed therapies for patients are made only in the context of prior consultation between the patient and physician. At a minimum, payers should continually update and ensure transparency by clearly describing their formulary design and preferred choice of biologic products.⁵

Most clinicians are concerned about high drug prices and the financial toxicity that they may impose both on their patients and the larger health care system, restricting or delaying access to effective

⁴ <https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/Prior-Auth-Position-Statement.pdf>

⁵ Rodriguez, G., Mancuso, J., Lyman, G. H., Cardoso, F., Nahleh, Z., Vose, J. M., ... & Sherwood, S. (2023). ASCO policy statement on biosimilar and interchangeable products in oncology. *JCO Oncology Practice*, OP-22.

therapies. Furthermore, clinicians understand that increasing competition through the approval of safe and effective biosimilars represents an opportunity to reduce costs and disparities in access to effective cancer treatments. Despite clinicians' efforts to keep patient costs as low as possible, desired patient outcomes are determined by the patient and the physician and payers should not play a role in choosing the most appropriate patient care.

Additionally, clinicians have the daunting task of explaining this new complex issue to their patients who may be uncomfortable with changing treatment from a more familiar agent. Clinicians must assess during conversations with their patients the benefit in prescribing a biosimilar, especially if the patient is stable and responding well to the reference product. The decision-making process becomes more complex with the existence of multiple biosimilars now available within the same drug class. This presents further challenges for clinicians in selecting the appropriate treatment for a patient and the rewriting of orders every time a patient is prescribed a biologic or biosimilar without prior knowledge of payer formularies.

Many clinicians in the United States believe that the selection of the appropriate biologic agent for their patients has largely been taken away by payers and pharmacy benefit managers (PBMs) increasingly motivated by financial incentives. In the United States, payers routinely switch their biosimilar formulary as CMS would allow in this proposal, raising concerns from clinicians about the appropriateness of multiple therapeutic changes on the same patient. With each payer establishing their own biosimilar formulary, oncology clinicians are required to keep a large inventory of multiple biosimilars in the same class at any given time, furthering the strain on financial and administrative resources.

By definition, a biosimilar is clinically equivalent to its reference product. An interchangeable biologic is not superior in quality and would have to meet the same regulatory requirements as a biosimilar. Interchangeability is simply a regulatory term that has created confusion about the inherent lack of clinically meaningful difference of a biosimilar. So, if a biosimilar is equivalent in structure, function, safety, and efficacy to the reference product, by definition, the two are interchangeable. By creating a divide between a biosimilar and an interchangeable biosimilar for regulatory purposes at the pharmacy level, the United States further exacerbates clinician and patient education and access barriers.⁶

For additional information please see our affiliate, the American Society of Clinical Oncology's Policy Statement on Biosimilar and Interchangeable Products in Oncology.⁷

⁶ Rodriguez, G., Mancuso, J., Lyman, G. H., Cardoso, F., Nahleh, Z., Vose, J. M., ... & Sherwood, S. (2023). ASCO policy statement on biosimilar and interchangeable products in oncology. *JCO Oncology Practice*, OP-22.

⁷ Rodriguez, G., Mancuso, J., Lyman, G. H., Cardoso, F., Nahleh, Z., Vose, J. M., ... & Sherwood, S. (2023). ASCO policy statement on biosimilar and interchangeable products in oncology. *JCO Oncology Practice*, OP-22.

Increase the Percentage of Dually Eligible Managed Care Enrollees Who Receive Integrated Medicare and Medicaid Services

ASCO supports CMS' proposal to offer additional opportunities for enrollment in plans that integrate Medicare and Medicaid and more opportunities to switch to Traditional Medicare. To achieve this, the proposed rule would revise the current quarterly special enrollment period (SEP) for dually eligible and other Part D low-income subsidy (LIS) enrolled individuals to a once-per-month SEP to enroll in a standalone prescription drug plan and create a new integrated care SEP, to allow dually eligible individuals to elect an integrated dual eligible special needs plan (D-SNP) on a monthly basis.

For dually eligible individuals, the two SEP proposals would allow a monthly election to:

- Leave an MA-PD plan for Traditional Medicare by enrolling in a standalone PDP,
- Switch between standalone PDPs, or
- Enroll in an integrated D-SNP such as a fully integrated D-SNP, highly integrated D-SNP, or applicable integrated plan.

Increasing the percentage of dually eligible Medicare Advantage Plan enrollees who are in plans that also cover Medicaid would expand access to integrated materials, unified appeal processes across Medicare and Medicaid, and continued Medicare services during an appeal for those individuals. ASCO is committed to supporting policies that allow individuals to access affordable insurance without interruption⁸, and we agree with CMS that the proposals discussed in this section have the potential to increase access to integrated Medicaid and Medicare coverage.

ASCO believes that all eligible individuals should be able to apply, enroll in, and receive coverage benefits in a timely and streamlined manner that promotes equitable coverage, especially for individuals with a cancer diagnosis, or who are at increased cancer risk. Efforts to preserve access to health insurance, given the integral link to health care access, can improve cancer health outcomes.⁹ Enrollment delays or restrictions result in disruptions in care, unanticipated treatment delays, and delays in screening and care, all of which are linked to worse cancer care outcomes. When patients are no longer able to access screening or other preventative care services, they may (knowingly or not) delay seeking treatment until their disease is at an advanced stage.¹⁰

Limit Out-of-Network Cost Sharing for D-SNP PPOs

The proposed rule would limit out-of-network cost sharing for Dual Eligible Special Need Plans (D-SNP) preferred provider organizations (PPOs) for specific services, including chemotherapy administration services, chemotherapy/radiation drugs, and radiation therapy integral to the treatment regimen, and

⁸ <https://www.asco.org/sites/new-www.asco.org/files/content-files/2017-ASCO-Principles-Healthcare-Reform.pdf>

⁹ Yabroff KR, Reeder-Hayes K, Zhao J, et al: Health insurance coverage disruptions and cancer care and outcomes: Systematic review of published research. *J Natl Cancer Inst* 112:671-687, 2020

¹⁰ Amini A, Jones BL, Yeh N, et al: Disparities in disease presentation in the four screenable cancers according to health insurance status. *Public Health*, 138, 50-56, 2016

other Part B drugs, beginning in 2026. **ASCO agrees with the agency that if finalized, this updated cost-sharing policy could expand dually eligible enrollees' access to providers, protect dually eligible enrollees from unaffordable costs, reduce cost shifting to Medicaid, and increase payments to safety net providers; therefore, ASCO strongly supports CMS' proposal.**

Full-benefit dually eligible enrollees who are not Qualified Medicare Beneficiaries (QMBs), are liable for cost sharing if they go out of network to providers not enrolled in Medicaid, as services from these providers are not covered by Medicaid unless the provider is enrolled in Medicaid. Cost sharing for out of network services is often much greater than cost sharing for in-network providers or for Traditional Medicare, and higher cost-sharing can prevent patients from accessing care. To protect beneficiary access to cancer care, we urge CMS to finalize this proposal.

We commend the Agency for including chemotherapy administration services and drugs in this updated policy. As CMS notes, these services are among those services for which D-SNP PPOs most often impose cost sharing greater than Traditional Medicare. Financial toxicity is particularly important for patients with limited financial resources who may be at risk of disproportionate harm because of cost-containment strategies deployed in oncology care. MA enrollees with cancer can be exposed to higher cost-sharing requirements for their drugs when they are administered by an out-of-network provider. Out-of-pocket expenses associated with cancer treatment may be substantial and lead to exhaustion of savings and personal bankruptcy. Moreover, these expenses have a disproportionate effect on those with lower incomes. ASCO supports the implementation of this proposal to contain cancer care costs while emphasizing high-value care.¹¹

In D-SNP PPOs most enrollees do not pay for Medicare services provided by Medicare providers, including out-of-network providers. When these enrollees access services, either State Medicaid agencies pay the cost sharing or, if state payment of cost sharing is limited by a Medicaid rate for the service that is lower than the amount the D-SNP would pay the provider, the provider must forego receipt of the cost sharing amounts. The cost sharing amounts for out-of-network services in D-SNP PPOs are often significantly higher than the cost sharing for the same services under original Medicare, which often increases the amount physicians and providers forgo. We agree with CMS that this effective payment cut could potentially disincentivize providers from serving dually eligible patients, which would in turn compromise access to care. ASCO supports CMS' proposal to limit out-of-network cost sharing for D-SNPs as it enables physicians and other providers to have adequate resources to continue providing high quality and equitable care.

Efforts to Protect Beneficiaries from Unfair Marketing Tactics

ASCO commends the Agency for its continued efforts to protect beneficiaries from predatory marketing tactics. The proposed rule aims to protect MA and Part D enrollees shopping for Medicare

¹¹<https://ascopubs.org/doi/full/10.1200/JCO.20.00642#:~:text=This%20updated%20statement%20affirms%20ASCO's,increasing%20awareness%20that%20results%20in>

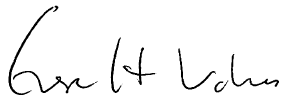
coverage from confusing and potentially misleading marketing while also ensuring they have accurate and necessary information to make coverage choices that best meet their needs. CMS is proposing to adopt compensation guardrails for agents and brokers and to require mid-year notification of benefits to beneficiaries among other proposals to protect beneficiaries.

Many beneficiaries rely on agents and brokers to help navigate complex Medicare choices as they comparison shop for coverage options. Medicare beneficiaries need accurate information from reliable sources about Medicare coverage without worry that they are being steered into a certain plan for the benefit of the agent, regardless of if a plan will meet enrollee needs. Enrollees should have a complete understanding of whether they will have access to their preferred providers and necessary prescriptions before enrolling in a plan and agents need to ensure they have this information. Enrollees applying for coverage should understand references to benefit information in plans and be able to use this information to make an informed plan selection with the help of a non-biased agent or broker.

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We appreciate the opportunity to comment on the 2025 Medicare Advantage and Part D Program proposed rule. Please contact Gina Hoxie (gina.hoxie@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,



Everett Vokes, MD, FASCO
Chair of the Board
Association for Clinical Oncology