Submitted Electronically at www.regulations.gov

February 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8013
Baltimore, MD 21244

Re: CMS–4201–P; 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

Dear Administrator Brooks-LaSure,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the 2024 Medicare Advantage and Part D proposed rule, which was published in the Federal Register on December 27, 2022.

ASCO is a national organization representing nearly 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 in Medicare Advantage

Since its founding more than 50 years ago, our affiliate, the American Society of Clinical Oncology (The Society), has been committed to addressing cancer health equity and continually works to improve understanding, advance scientific knowledge, and develop solutions to eliminate disparities in cancer care and outcomes. The Society strives, through research, education, and promotion of the highest quality equitable patient care, to create a world

where cancer is prevented, and every survivor is healthy. In this pursuit, cancer health equity remains a guiding institutional principle that applies to all its activities across the cancer care continuum. The Society's statement[1] on health equity affirms its commitment to moving beyond descriptions of differences in cancer outcomes and toward the achievement of cancer health equity. This includes a focus on improving equitable access to care, improving clinical research, addressing structural barriers, and increasing awareness that results in measurable and timely action toward achieving cancer health equity for all.

The Association applauds efforts the agency has made to address and reduce health disparities through policy updates and changes in this proposed rule. The Association supports the proposed changes discussed below.

ASCO supports CMS' proposal to require MA plans to provide culturally competent care to an expanded list of populations adversely affected by persistent poverty or inequality.

Although current regulations already require MA organizations to provide services in a culturally competent manner, Centers for Medicare & Medicaid Services (CMS) proposes to specify that this includes underserved groups beyond linguistically and culturally diverse populations. The proposed new list would be as follows: (i) people with limited English proficiency or reading skills; (ii) people of ethnic, cultural, racial, or religious minorities; (iii) people with disabilities; (iv) people who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (v) people who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (vi) people who live in rural areas and other areas with high levels of deprivation; and (vii) people otherwise adversely affected by persistent poverty or inequality.

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.[2]

ASCO agrees with CMS that the proposed list of populations better reflects the broad scope of underserved populations in Medicare Advantage (MA) plans who need culturally competent care. As the populations that CMS serves become increasingly diverse, it is imperative to keep regulations updated to ensure broad protections are available that minimize the potential for discriminatory barriers.

ASCO supports CMS' proposal to require MA organizations to identify and offer digital health education to enrollees with low digital health literacy to assist them with accessing any medically necessary covered telehealth benefits.

[1] https://ascopubs.org/doi/full/10.1200/JCO.20.00642?af=R
[2] NCI: Understanding Cancer Disparities, 2018. https://www.cancer.gov/about-cancer/understanding/disparities

Under this proposal, MA organizations would introduce a digital health literacy screening program or other similar procedure to identify current enrollees with low digital health literacy. Once the MA organization determines which enrollees experience low digital health literacy, the MA organization would then have to implement a digital health education program to offer to these enrollees.

Patient education efforts by healthcare stakeholders should include information on utilizing telemedicine.[3] Despite general availability and widespread use of internet services, many individuals in the United States lack access to or are not proficient in the use of information technology. This gap has led to inequities in the effective use of telemedicine for certain patients.[4] Individual differences in digital literacy can widen health disparities.[5,6,7] These inequities are especially present among individuals living in rural communities, individuals with lower socioeconomic status and older adults, who typically experience the majority of cancer diagnoses and deaths and make up the majority of cancer survivors and the fastest growing segment of the US population.[8,9,10] Addressing these disparities will be critical to realizing the promise of telemedicine for patients with cancer.

ASCO supports CMS' proposal to require MA organizations to incorporate one or more activities into their overall Quality Improvement (QI) program that reduce disparities in health and health care among their enrollees.

CMS is proposing to require MA organizations to incorporate one or more activities that reduce disparities in health and health care across the broad spectrum of QI program requirements. Examples of these activities include improving communication, developing and using linguistically and culturally appropriate materials (to distribute to enrollees or use in communicating with enrollees), hiring bilingual staff, community outreach, or similar activities. ASCO supports activities such as these to ensure high-quality, equitable care for cancer patients.

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[3] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-ASCO-Interim-Position-Statement-Telemedicine-FINAL.pdf

[4] Makri, A. (2019) 'Bridging the digital divide in health care', The Lancet Digital Health. Elsevier BV, 1(5), pp. e204–e205. doi: 10.1016/s2589-7500(19)30111-6.

[5] Pennell NA, Dicker AP, Tran C, et al. mHealth:Mobile Technologies to Virtually Bring the Patient Into an Oncology Practice. 2017 ASCO Educational Book. https://ascopubs.org/doi/full/10.1200/EDBK_176093

[6] NelsonR, Joos I, WolfDM. Social Media for Nurses: Educating Practitioners and Patients in a Networked World. New York, NY:Springer Publishing Company;2013.

[7] Sclafani J, Tirrell TF, Franko OI.Mobile tablet use among academic physicians and trainees. J Med Syst. 2013;37:9903

[8] Hurria A, Levit LA, Dale W, Mohile SG, Muss HB, Fehrenbacher L, et al. Improving the evidence base for treating older adults with cancer: American society of clinical oncology statement. J Clin Oncol 2015;33:3826–33.

[9] Kutner M, Greenburg E, Jin Y, Paulsen C. The health literacy of America's adults: results from the 2003 national assessment of adult literacy. National Center for Education Statistics; 2006. Report No.: NCES 2006-483. https://nces.ed.gov/pubs2006/2006483.pdf

[10] https://deepblue.lib.umich.edu/bitstream/handle/2027.42/151376/NPHA_Telehealth-ReportFINAL-093019.pdf?sequence=4&isAllowed=y

Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Mandate Annual Review of Utilization Management Tools

Prior Authorization

Many provider organizations have reported that the prior authorization process is a significant source of burden for patients, providers, and payers. It contributes to provider burnout and poses a health risk to patients when it delays their care. Disparate payer policies, provider workflow challenges, and technical barriers all contribute to this burden.

As highlighted in the April 2022 report by the Office of Inspector General (OIG) prior authorization policies can limit beneficiaries' access to care.[11] To strengthen beneficiary access, CMS needs to take significant action to streamline prior authorization (PA). Plans use utilization management techniques, including prior authorization, to restrict or deny coverage, undermining patient access to diagnostics and medically necessary care. Patients with cancer often face delays in approval for treatment, and many oncology drugs do not have substitutes that are both equally effective and less expensive for a given patient. Consequently, policies that attempt to incentivize, force, or coerce patients to accept anti-cancer therapy alternatives that are not recommended by their oncologist can threaten both the outcomes for patients and the well-being of their families or caretakers.

ASCO recently published the results of a survey[12] of our members in the United States to assess the impact of prior authorization on cancer care. The survey results show three main takeaways: prior authorization is delaying patient care, impacting cancer care outcomes, and diverting providers from patient care.

Nearly all survey participants reported a patient has experienced harm because of prior authorization processes, including significant impacts on patient health such as disease progression (80%) and loss of life (36%). The most widely cited harms to patients reported were delays in treatment (96%) and diagnostic imaging (94%); patients being forced onto a second-choice therapy (93%) or denied therapy (87%); and increased patient out-of-pocket costs (88%).

We commend CMS for taking initial action to address concerns governing prior authorization, utilization management, and medical necessity determinations in MA. We offer our comments and recommendations on select proposals below. ASCO would like to collaborate closely with the agency to ameliorate prior authorization policies to protect beneficiary access to appropriate, life-saving care and to relieve administrative burden.

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[11] U.S. Department of Health and Human Services Office of Inspector General. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care, OEI-09-18-00260. Available at https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

[12] ASCO Prior Authorization Survey Summary. Available at: https://old-prod.asco.org/sites/new-www.asco.org/files/ASCO-Prior-Auth-Survey-Summary-November-2022.pdf

CMS has proposed to codify standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than Traditional Medicare. MA Plans must comply with National Coverage Determinations (NCD), Local Coverage Determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes and regulations as interpreted by CMS. This includes coverage instructions and guidance in Medicare manuals, instructions, and other guidance documents. ASCO supports this proposal.

We agree with CMS that MA organizations should follow and comply with CMS's interpretation of Medicare laws and coverage requirements as reflected in the manuals, guidance, and instructions issued by CMS to ensure that all Medicare beneficiaries have access Medicare covered services regardless of the plan in which they are enrolled. The OIG report found that 13 percent of prior authorization denials within the MA program were for service requests that met Medicare fee-for-service coverage rules, likely delaying or preventing necessary patient care. Medicare beneficiaries should have equal access to the same services, regardless of the plan they choose.

We agree with CMS that when an MA organization is deciding whether an item or service is reasonable and necessary for an individual patient, MA organizations should make medically necessary decisions in a manner that most favorably provides access to services for beneficiaries and aligns with CMS's definition of reasonable and necessary.

ASCO supports CMS' proposal to limit MA organizations' discretion to require alternate services or settings. When care can be delivered in more than one way or setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MA organization may not deny coverage of the services or setting unless they fail to meet the regulatory criteria described above. The patient and physician work together to determine the best care plan, including where the patient will receive the services. These determinations are made for personal reasons and should not be dictated by the MA organization.

CMS has proposed that in situations when no applicable Medicare statute, regulation, NCD, or LCD establishes when an item or service must be covered, MA organizations must include current evidence in widely used treatment guidelines or clinical literature when creating internal clinical coverage criteria. MA organizations must make this evidence publicly available to CMS, enrollees, and providers. CMS solicits comment on the definition of widely used treatment guidelines and clinical literature that would justify internal coverage criteria used in the absence of NCDs, LCDs, or Traditional Medicare statutes or regulations.

The Medicare Benefit Policy Manual, Chapter 15, §50.4.5 instructs Medicare Part B contractors to not deny coverage of an FDA approved drug or biological, used in an anti-cancer chemotherapy regimen, if such drug's use is supported by any of the following compendia and not listed as unsupported by any of the following compendia: American Hospital Formulary Service-Drug Information, National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Micromedex DrugDex, Clinical Pharmacology, and Lexi-Drugs. MA organizations must follow off-label, medically accepted indications included in these compendia to ensure that basic benefits coverage for MA enrollees is no

more restrictive than Traditional Medicare. **ASCO supports policy that requires MA organizations to cover all off-label indications supported by the approved compendia for anti-cancer chemotherapy regimens.**

§50.4.5 further allows contractors to identify additional indications through use of peer-reviewed medical literature from a list of 26 publications. §50.4.5 provides guidance on how to evaluate evidence within medical literature. **ASCO supports policy that requires MA organizations to consider peer-reviewed medical literature included in the list of approved publications for anti-cancer chemotherapy regimens.**

If finalized, MA organizations must provide publicly available information that discusses the factors the MA organization considered in making coverage criteria for medical necessity determinations. MA plans should provide a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. **ASCO supports policy that requires payers to disclose the process by which they evaluate and determine prior authorization, including the evidence on which these decisions are based.**[13]

ASCO recommends that ASCO guidelines[14] be included in establishing clinical coverage criteria and that prior authorization should not be required for pathway and/or guideline concordant care. "Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[15] Clinical guidelines contain recommendations that are based on evidence from a rigorous systematic review and synthesis of the published, peer-reviewed, medical literature. Physicians follow guidelines for the same reason that CMS is proposing that payers use them when establishing coverage criteria. Prior authorization should not be required in this instance, obviating the need for payers to spend resources developing internal coverage criteria based on guidelines practitioners are already following.

ASCO strongly supports CMS' proposal to make a prior authorization approval valid for the duration of the approved course of treatment and/or the duration of the prescribed order, as decided on by the physician and patient. CMS proposes to provide a minimum 90-day transition period when an enrollee switches plans; however, ASCO recommends that CMS prohibit mandatory substitution or interruptions in treatment that is already underway.

[13] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2022-PA-Statement-FINAL.pdf
[14] https://old-prod.asco.org/practice-patients/guidelines
[15] Institute of Medicine (US) Committee to Advise the Public Health Service on Clinical Practice Guidelines. Clinical Practice Guidelines: Directions for a New Program. Field MJ, Lohr KN, editors. Washington (DC): National Academies Press (US); 1990. PMID: 25144032.

Cost control methods employed by payers interfere with the doctor-patient relationship—and, ultimately, quality of care.[16] When a provider plans a course of therapy, it requires careful consideration and collaboration with the patient and should not be interrupted by a payer for cost-control reasons. When an enrollee changes plans and must resubmit a prior authorization request, this can delay or interrupt treatment that has already been deemed clinically appropriate. Requiring both payers and providers to repeat an already burdensome process creates additional strain on the healthcare system.

CMS has proposed to require that the healthcare professional conducting a medical necessity review have expertise in the field of medicine that is appropriate for the item or service being requested before an MA organization or applicable integrated plan issues an adverse determination. While we support a review prior to a denial of a prior authorization request, ASCO is concerned that the physician or other appropriate health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider.

A significant burden within the prior authorization process is "peer-to-peer" communication, usually conducted over the telephone, with the physician sharing more in-depth clinical information with a healthcare provider employed by the payer. For many providers, this is the step in the process that can be the most time-consuming and frustrating, in many cases occurring with a "peer" who lacks expertise in the specific clinical area under discussion (i.e., in the case of cancer treatment, a non-oncologist). **ASCO urges CMS to require payers to ensure that during "peer-to-peer" discussions or other discussions of clinical circumstances, the treating oncologist has direct access to an oncologist employed by or otherwise authorized by the payer to make prior authorization determinations in cancer care.**

ASCO supports CMS' proposal to require all MA Plans to establish a Utilization Management Committee to review all utilization management, including prior authorization, policies annually and ensure they are consistent with current, traditional Medicare's national and local coverage decisions and guidelines; **however, we believe that CMS needs to take a more proactive role in the enforcement and oversight of the proposals in this rule.**

ASCO recommends that CMS and other regulatory agencies should monitor and remedy the predictable, adverse consequences that individuals with cancer may experience from barriers or delays in receiving preferred oncology therapies as a result of prior authorization requirements, including suboptimal clinical outcomes, increases in adverse events, increases in emergency department visits, and disparities in treatment or outcomes. Additionally, regulators should develop and implement a provider complaint portal to report and monitor payer practices that negatively impact patients. While we appreciate that CMS is making changes to improve prior authorization in MA, CMS and other regulators need to take action to ensure payer compliance with these policies.

[16] 2 American Society of Clinical Oncology: American Society of Clinical Oncology Position Statement: Pharmacy benefit managers and their impact on cancer care. https://www.asco.org/sites/new-www.asco.org/files/contentfiles/advocacy-and-policy/ASCO-Position-Statement-PBMs-Aug.-2018.pdf?et_cid=40510620&et_rid=1760459169&linkid=the+statement.

CMS solicits comment on whether a utilization management (UM) committee should be required to ensure that the UM policies and procedures are developed in consultation with contracted providers; whether the UM committee should ensure that MA organization communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees.

ASCO agrees with CMS that physicians participating in a MA Plan's network should be well represented on the Plan's UM Committee.

The Proposed Rule requires that a MA Plan must revise UM policies and procedures as necessary, and at least annually. The governing statute requires a MA plan to disclose to potential enrollees the services subject to prior authorization "at the time of enrollment." Allowing MA Plans to add prior authorization requirements to additional services during the plan year would undermine the intent of this statutory provision. **For this reason, we urge CMS to clarify that only new services not available at the time of enrollment can be added to the list of services that require PA.**

CMS solicits comment on whether the proposed regulatory provisions sufficiently address the requirements and limits that the agency describes in the preamble. We thank CMS for addressing prior authorization in MA. We understand these proposals come in the wake of the April 2022 report by the Office of Inspector General (OIG) raising concerns about MA plans' denials of requests for prior authorization. We urge CMS to also incorporate ASCO and other stakeholder feedback in this rule and in future rule-making cycles as we continue working to prevent delays in patient care and improve cancer care outcomes. For additional information, please read our affiliate The Society's, Position Statement on Prior Authorization, which can be found here.[17]

ASCO strongly urges CMS and other regulatory agencies to:

- Require payers to improve transparency by mandating payers to report to CMS and the public on the extent to which they use prior authorization by disclosing the process by which they evaluate and determine prior authorization and hold payers accountable for the timeliness of determinations. ASCO will submit comments in response to the Electronic – Prior Authorization proposed rule, but we reiterate our comments here. Payers need to be held accountable and provide prior authorization notifications within the set timeframe. **If the physician does not receive a decision within the set timeframe, the default response should be an approval of the prior authorization request.**
- Establish efficient and responsive appeals processes, including 48-hour completion of review/decision on appeals for oncology and expedited review for patients whose clinical circumstances require urgent treatment. Any delay in appropriate cancer care can be devastating to patients and result in disease progression or serious impairment of quality of life.
- 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

[17] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2022-PA-Statement-FINAL.pdf

disadvantage them. Hispanic and Latinx patients were less likely to fill a prescription compared to White patients (31% vs 44%) after a claim was rejected by prior authorization.[18] Consistent with a previous survey conducted by the American College of Cardiology in 2016,[19] the Association of Black Cardiologists found that almost all physicians (98%) experience a barrier when prescribing new evidence-based therapy, with the most prevalent issues being cost (78%) and prior authorization documentation/administrative burden (75%).[20] To prevent exacerbating health disparities and to bolster the work of the agency[21] and the Administration to reduce health disparities, the need for a more transparent, efficient prior authorization process is critical—especially for smaller, under-resourced providers and their patient populations.

Step Therapy

ASCO is disappointed that CMS did not make any improvements to its step-therapy policy. Step therapy is a utilization management approach that requires patients to use the payer's preferred drug before the payer will cover another drug that may be preferred by the patient and treating physician. Commonly referred to as "fail-first" policies, patients must demonstrate that the payer-preferred product has been unsuccessful before proceeding with the regimen initially recommended in consultation with the treating physician. The most common use of the phrase "step therapy" refers to policies based solely or in large part on whether two or more drugs fall within the same class or category of drug. The relative cost of drugs within the same category or class is the main driver for classification of "preferred" therapies. Step-therapy policies are generally inappropriate in oncology due to the individualized nature of modern cancer treatment and the general lack of interchangeable clinical options.

Medically appropriate cancer care demands patient access to the most appropriate drug at the most appropriate time. According to our affiliate organization, The Society,[22] **a better approach to utilization management is adoption of high-quality clinical pathways or coverage policies based on robust analyses of best clinical practices and existing scientific data.** Such clinical pathways or medical coverage policies may recommend or require that oncologists start with one or more drugs prior to using other therapeutic options. Properly designed clinical pathways and coverage policies should

[18] American Journal of Managed Care. Expert Panel Offers Insight Into Multifaceted Approach to Addressing Health Care Disparities. https://www.ajmc.com/view/expert-panel-offers-insight-into-multi-faceted-approach-to-addressing-health-care-disparities
[19] American College of Cardiology. Cardiologist Perceptions of Access to New Therapies. October 2016.
[20] The ABC Access to Care Initiative Prior Authorization Work Group. Identifying How Prior Authorization Impacts Treatment of Underserved and Minority Patients.Association of Black Cardiologists. 2019. Available from: http://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf.
[21] https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity
[22] American Society of Clinical Oncology Policy Statement On the Impact of Utilization Management Policies for Cancer Drug Therapies. Available at: https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2017-ASCO-Utilization-Management-Statement.pdf

adhere closely to the recommendations described in the policy statement, and well-designed policies should not require 100 percent concordance.

Gold Carding

For years, ASCO has advocated at the federal and state level for a more streamlined prior authorization process to stop delays in care that negatively impact patients with cancer and contribute to administrative burden. To this extent, ASCO has long supported state and federal regulations and legislation that seek to set a threshold for prior authorizations where the item or service is approved a vast majority of the time, such as gold carding.

ASCO recommends that state and federal governments strengthen oversight and require insurers to implement gold carding when providers have a proven track record of prior authorization approvals. Gold carding programs have the potential to resolve many provider concerns related to prior authorization. However, monitoring and real-world experience will be required before the cancer care community can consider them a panacea. For additional information, please read our policy brief on gold carding.

Medicare Advantage Network Adequacy: Access to Services

ASCO supports CMS' proposal to require MA organizations offering coordinated care plans to arrange for any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

MA may be an attractive option for Medicare beneficiaries; however, these patients may face unexpected financial harm when diagnosed with cancer. While MA plans may charge a lower premium than the combination of Traditional Medicare, Medigap and Part D coverage, 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.

Patients should not be penalized when a MA network is not adequate to provide necessary and life-saving care and treatment. The responsibility of maintaining a strong network falls on the MA organization, and when it fails, the patient should be entitled to in-network cost sharing.

Updating Translation Standards for Required Materials and Content

CMS has proposed to require MA organizations and Part D sponsors to translate materials into any non-English language on a standing basis that is the primary language of at least 5 percent of the individuals in a plan benefit package service area. ASCO supports this proposal.

ASCO also supports CMS' proposal to communicate with enrollees using their language of choice. Once a plan learns of an enrollee's preferred language – whether through an enrollee requesting a material in a preferred language, during a health risk assessment, or another touch point – the plan must provide required materials in that language and/or accessible format if the enrollee remains enrolled in the plan or until the enrollee requests that the plan provide required materials in a different manner.

To support all Medicare beneficiaries and to improve health equity, CMS should ensure that MA plans provide communication materials that are culturally appropriate and address the specific communication and language assistance needs of MA beneficiaries.

Medicare Advantage and Part D Marketing

Following congressional and press attention to MA marketing practices, including a recent US Senate Finance Committee report that detailed deceptive marketing practices by MA plans, CMS proposes changes to the rules governing MA and Part D marketing. The proposed rule aims to protect MA and Part D enrollees and people shopping for Medicare 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. **ASCO supports CMS' efforts to protect Medicare beneficiaries from misleading and confusing marketing.**

Medicare beneficiaries need accurate information about Medicare coverage, and they need to know how to access this information from available sources. Enrollees should have a complete understanding of whether they will have access to their preferred providers and necessary prescriptions before enrolling in a plan. Plans must also make clear to Medicare beneficiaries what choices and options they will lose when switching between Traditional Medicare and different types of MA plans.

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. Information included in plan marketing names should match the information included in the Plans & Benefits Template, the Summary of Benefits, or other information submitted during the certification process. Furthermore, MA plans must not implement marketing practices that discourage enrollment by individuals with significant health needs.

Changes to an Approved Part D Formulary – Immediate Substitutions

ASCO opposes CMS' proposal to permit Part D sponsors to make immediate formulary changes by substituting:

- **a new interchangeable biological product for its corresponding reference product**
- **a new unbranded biological product for its corresponding brand name biological product**
- **a new authorized generic for its corresponding brand name equivalent**

If finalized as proposed, Part D sponsors meeting certain requirements could provide notice of these specific changes, including direct notice to affected beneficiaries, *after* they take place and would not need to provide a transition supply of the substituted drug.

Substitution is the practice of dispensing an interchangeable product to any given patient at the pharmacy level without consulting the prescriber. State laws generally uphold the authority of the physician to make final treatment decisions, including determinations of medical necessity and non-substitution. Although the FDA designation of interchangeable in the setting of biologic treatment means that the biologic product may be substituted without the intervention of the prescribing provider, physicians and patients should be aware of product substitutions so that they can make informed treatment decisions.

Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act

The Medicare statute requires that entities report and return any overpayment within 60 days of when the overpayment is identified. The proposed rule would revise the definition of when an overpayment is "identified." The proposal would provide that "[a] person has identified an overpayment when the person knowingly receives or retains an overpayment." The proposal references the False Claims Act definition of "knowingly," which extends to actual knowledge, reckless disregard, and willful blindness.

ASCO recommends that CMS reconfirm in the final rule that physicians and practices will have a reasonable amount of time to quantify the amount of the overpayment before the 60-day time period begins. Under current regulations, providers generally return the overpayment approximately 8 months after receipt of the payment. The overpayment amount is quantified within approximately 6 months, and then the overpayment is returned within the following 60 days. Quantifying the overpayment and returning it within 60 days would require resources and personnel that are currently not in place, creating additional burden and stress on physicians and practices.

Complications may arise when identifying overpayments that sometimes extend beyond one claim. Coding issues, complications with Stark Laws, and other extenuating circumstances may stretch beyond the initial issue and require time to accurately address. As CMS acknowledges in the proposed rule, it is not uncommon for it to take several months, if not more, for a provider or supplier to determine the amount of an overpayment. Additionally, it is not possible for a provider to return an overpayment if the amount of the overpayment remains unknown. ASCO recommends that CMS provide clarifying language in the final rule.

Part D Sponsor Website Requirements

CMS proposes that the utilization management criteria used by a Part D sponsor, as approved by CMS, must be posted on the plan's website prior to the plan year. The regulation currently indicates that utilization management forms must be posted; however, utilization management criteria are distinct from the forms used to submit a coverage determination to satisfy the criteria. ASCO supports this

proposal.

The lack of transparency in the prior authorization process makes it difficult for providers and patients to evaluate the effectiveness, potential impact, and costs of prior authorization processes. To ensure that patients and health care providers are fully informed while purchasing a product and/or making care decisions, payers need to be transparent about all coverage and formulary restrictions and the supporting clinical documentation needed to meet prior authorization requirements. Knowing what requirements are needed in advance of providing vital health care services is critical to ensuring timely access to care for patients.

Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program

ASCO supports CMS' proposal to implement section 11404 of the Inflation Reduction Act (IRA), which expands eligibility under the Low-Income Subsidy program. Under the IRA provision and proposal, individuals with incomes up to 150 percent of the federal poverty level and who meet statutory resource requirements will qualify for full low-income subsidies beginning on or after January 1, 2024. This change will provide a full subsidy to those who currently qualify for the partial subsidy, improving affordability of prescription drug coverage for these Medicare enrollees.

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We appreciate the opportunity to comment on the 2024 Medicare Advantage and Part D 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,

Lori Pierce, MD, FASTRO, FASCO
Chair of the Board
Association for Clinical Oncology