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Via Electronic Submission

January 25, 2019

Seema Verma

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

200 Independence Ave, S.W.

Washington, DC 20201

Re: CMS-4180-P. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma:

The American Society of Clinical Oncology (ASCO) is pleased to provide comment on the proposed amendments to the Medicare Advantage (MA) and Prescription Drug Benefit (Part D) programs, which were published by CMS in the Federal Register on November 26, 2018. ASCO is the national organization representing more than 45,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members 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, including Medicare beneficiaries.

As cancer care evolves and advances continue to increase the proportion of orally administered anticancer drugs, ensuring appropriate access to treatment for Medicare beneficiaries is critical. Traditionally, intravenous cancer therapies have been provided and reimbursed by Medicare through the Part B benefit. With the introduction of more orally administered therapies, new challenges arise associated with coverage and reimbursement of cancer treatments under Part D.

This rise in orally administered cancer therapies has created new difficulties in securing patient access to the most appropriate treatment at the most appropriate time for their diagnosis and unique clinical condition. We reaffirm our support for the strong “protected class” standard that requires each unique antineoplastic molecular entity to be covered by each Part D plan’s formulary. Additionally, ASCO members have significant concerns about the unnecessary

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administrative burdens imposed by existing utilization management policies, some of which have interfered with timely delivery of appropriate care. We strongly oppose any expansion of authority that would allow PBMs and plan sponsors to impose barriers to effective patient care.

CMS must ensure appropriate and timely access to cancer therapies for all Medicare beneficiaries. ASCO's concerns with the proposed changes are summarized below.

- **CMS should maintain the protections originally granted in statute and regulation for the six protected classes of drugs under Medicare Part D. ASCO opposes any changes that would impede access to necessary cancer treatment or result in interruption of treatment for cancer patients.**
- **ASCO strongly opposes step therapy policies and similar policies that create barriers and delays to patient access to care. CMS should consider the use of oncology clinical pathways in lieu of step therapy to guide delivery of high-quality cancer care.**
- **CMS should require a detailed accounting of direct and Indirect Remuneration (DIR) fees. We ask that CMS prohibit the use of measures and standards that are not specific to oncology, but that are used in determining performance-related payments for oncology dispensing physicians and practice-based pharmacies.**
- **ASCO supports the idea of an integrated real-time benefits tool to support beneficiary-specific decision-making. These tools should include both cost and clinical, evidence-based information to support value-based treatment decisions.**

The following provides additional details on these recommendations.

CMS should maintain the protections originally granted in statute and regulation for the six protected classes of drugs under Medicare Part D. ASCO opposes any changes that would either impede access to—or interrupt—necessary treatment for patients with cancer.

In establishing the six protected classes of drugs, Congress took the necessary steps to ensure that all beneficiaries have access to necessary medications and that vulnerable populations are not discouraged from enrolling in specific Part D plans because of formulary design related to treatments for specific conditions. CMS' original interpretation of the statute, and subsequent policies, recognized the danger of risks and complications associated with an interruption of therapy for these vulnerable populations. While we appreciate the Administration's interest in making prescription drugs more affordable for beneficiaries through this new policy, we believe this proposal is misguided, and the original protections granted in statute and regulation must be maintained going forward.

Medicare beneficiaries need access to medically-appropriate prescription drugs to treat their diseases and conditions, and cancer care decisions should be determined by the medical team and the patient. However, there is increasing interference by plan sponsors and PBMs, including non-medical switching, delays in responding to prior approval requests and deliveries of incorrect prescriptions. Providers are accountable for quality outcomes, and it is important

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to understand that cost containment strategies in use by plan sponsors and PBMs can affect patients in ways beyond a provider's control.

We are deeply concerned about proposed utilization management tactics triggered by non-protected class indications, exclusions for new formulations, and price increases. These are driven by cost instead of more appropriate reliance on clinical evidence. Regardless of the trigger allowing plans to impose utilization management, no such utilization management policy should be implemented to the detriment of clinical patient care. Additionally, if these cost factors result in non-coverage of certain drugs under this policy, Medicare beneficiaries will bear the full cost of treatment.

ASCO strongly opposes step therapy policies and similar policies that require demonstration that the plan preferred drug does not work before allowing use of medication recommended by the provider. This could result in serious harm to patients with cancer, including diminishing or precluding chances for a successful outcome. CMS should consider the use of oncology clinical pathways in lieu of step therapy as a way to guide delivery of high-quality cancer care.

In practice, step therapy is a utilization management tool that requires patients to try and fail medications chosen by a payer before the payer will cover the medication originally prescribed by their health care provider. During this process, patients must demonstrate that the payer-preferred treatment, which is not always the most appropriate for the patient, has been unsuccessful in treating their condition before they are able to move on to the physician recommended drug. Due to the try and fail nature of this policy approach, it is also commonly referred to as a "fail first" protocol.

Step therapy policies are inappropriate for use in oncology treatment due to the individualized nature of modern cancer treatment and the general lack of interchangeable clinical options. Furthermore, these policies are particularly problematic for patients with cancer because they can severely delay a patient's access to the best treatment available for their condition. While many treatments preferred by payers are less costly financially, they may not be the best treatment available for the patient. While waiting to complete a "step", a patient with cancer can experience disease progression and irreversible damage to their overall health. Ultimately, the total cost of care for the patient increases.

Step therapy disregards the provider-patient relationship, reduces health care quality, burdens patients with cancer and their providers, and can increase health care costs. Although payers attempt to reduce health care costs through step therapy protocols, fail first policies can negatively impact patient health and increase the overall cost of the patient's care. For these reasons and those outlined in ASCO's policy statement on Utilization Management¹, ASCO strongly opposes step therapy policies and similar policies that create barriers and delays to

¹ American Society of Clinical Oncology, American Society of Clinical Oncology Policy Statement On the Impact of Utilization Management Policies for Cancer Drug Therapies. April 2017. Available at: <http://www.asco.org/sites/new-www.asco.org/files/content-files/04.18.17-Utilization-Management-Statement.pdf>

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patient access to care.

As mentioned above, plan sponsors have already implemented step therapy policies that have resulted in limiting access to cancer therapies and delays in care. ASCO previously has raised objections with the August 7, 2018 policy memorandum giving MA plans the option to apply step therapy for Part B drugs. We have similar concerns about this rule proposing to codify the 2019 option. Expanding sponsors' authority to make decisions solely based on cost, and without regard for clinical evidence, will continue to have serious unintended consequences on the quality of care cancer patients receive.

Having been given authority in the 2018 memo, at least one Medicare Advantage plan is imposing step therapy policies in the 2019 plan year for several cancer drugs. As authorized, these policies appear to be based on cost savings and not clinical considerations. At least one preferred drug is a biosimilar, and currently there are no approved "interchangeable" biosimilars; as a result, this policy is limiting access. Furthermore, these policies have not adequately incorporated safeguards to allow access to necessary treatment based on important clinical, patient specific considerations including the requirement for plans to consider limitations on treatment options, contraindications, expectations of specific outcomes and adverse reactions.

CMS should consider the use of oncology pathways to promote high-quality, high-value medical oncology care. Clinical treatment pathways select a preferred, evidence-based therapeutic option based upon efficacy and toxicity, and only consider costs if the efficacy and toxicity of two or more drugs are equally acceptable in the clinical situation. This promotes consistent use of treatments with demonstrably high value and avoids costs related to unnecessary or inappropriate care.

Validation of pathways through some form of credentialing or deeming process will be important to ensure that pathways are based on scientific evidence and promote the best interests of patients. Pathways also provide a valuable mechanism to collect comparative data on drugs with similar efficacy and toxicity profiles. Pathways are also an effective way to assure that every patient, regardless of setting or geography, can benefit from the most current recommended care. Overall, the use of clinical treatment pathways in lieu of more traditional utilization management techniques will lead to better outcomes for patients while supporting oncology care providers in making care decisions based on the best evidence available and avoiding drug wastage.

CMS should require a detailed accounting of direct and indirect remuneration fees and prohibit the use of measures and standards that are not specific to oncology in determining performance-based payments to oncology dispensing physicians and practice-based pharmacies.

Collection of retroactive fees, known as direct and indirect remuneration (DIR) fees, have a negative and unpredictable impact on oncology practice. CMS implemented DIR fees in Medicare Part D to set drug reimbursement at the lowest price, once the actual net cost of drugs has been determined. Typically, these fees would reflect additional concessions received

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by the PBM after the point-of-sale and are reported to ensure CMS is aware of the final cost of drugs.

Recently however, PBMs have created a separate and additional DIR fee structure, known among pharmacists and physicians with in-office dispensing as “claw backs.” These fees are based on physicians’ and pharmacists’ performance against certain -- and often unknown -- metrics. The CMS Star Rating System, which is used to measure Medicare Part D plan performance, is used to measure performance and determine DIR fees. The Star Rating System generally measures medication adherence for conditions such as diabetes, hypertension, and cholesterol. The Star Rating System does not include medication management measures in oncology. Importantly, these measures are not designed to measure pharmacy providers or physicians, and do not include measures for medication management in oncology.² Nevertheless, DIR fees are charged to oncology providers based on the Star Rating, and the methodology for determining the fees is not transparent to providers. These performance-based fees are not required by HHS or CMS regulations, and appear to have no basis in statute.³

CMS should ensure that quality measures relating to cancer care focus on the specifics of cancer treatment, are meaningful to patients and relevant in all oncology disciplines or specialties. For more than a decade, ASCO has offered to its members the Quality Oncology Practice Initiative (QOPI®), a comprehensive quality program that includes robust, oncologist-developed quality measures, which allows providers to report clinically relevant quality measures for cancer care that promote value and protect patients during cancer treatment.

CMS should promote Medicare quality by instructing plan sponsors and PBMs to discontinue application of current Star performance ratings and related DIR claw backs on oncology dispensing physicians and practice-based pharmacies, instead relying on measures and standards that are more appropriate to the specialty. Additionally, if the intention is to drive lower costs, these collected fees should be reported to CMS, so that the full extent of discounts and other revenue generated by PBMs is fully transparent and considered in reimbursement policies.

ASCO supports the idea of an integrated real-time benefits tool to support beneficiary-specific decision-making. These tools should include both cost and clinical, evidence-based information to support value-based treatment decisions.

Cancer patients bear an enormous amount of out-of-pocket expenditures, in the form of cost-sharing for drugs or full liability for non-covered drugs. As a result, cancer patients are often at risk of financial toxicity related to the cost of their care. This can have a critical impact on health care decision-making, and overall quality of care. Patients with cancer are more likely than people without a cancer history to modify their behaviors as a result of these hardships

² Centers for Medicare and Medicaid Services. 2018 Part C and D Star Ratings Measures. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2018MeasureList.pdf>

³ 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.

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and are more likely to report delayed prescription filling, use of less medication, or skipped medication doses⁴. Patients and physicians would benefit from access to real-time information about the cost of treatment at the point of care to avoid the unintended consequences associated with high out-of-pocket costs.

CMS should pursue policies that facilitate development and incentivize use of real time benefit tools (RTBT) to provide meaningful information on the value of drug therapies at the point of care. Such tools would support the most appropriate therapeutic choices for patients and physicians. To be effective, however, providers must be willing to adopt a solution, which means factoring another technology into their workflow. For this reason, it is important that physicians do not encounter additional burden in implementing such systems. Many practices currently struggle with integration of data into current electronic prescribing and EMR systems and adding additional requirements across various payers will prove burdensome to physicians. Moreover, RTBT will need to provide the elements that are important to oncologists and their patients, such as cash price, patient assistance programs, prior authorization requirements and medication alternatives. (Source: <https://www.covermymeds.com/main/insights/rtbc-scorecard>.) As noted in the CMS proposal, RTBT standards are currently in development, led by the National Council for Prescription Drug Programs (NCPDP). Currently these standards do not account for some functionality providers indicate they value most in an RTBT solution, including cash price and availability of patient assistance programs. It is important that oncology provider and patient groups provide input into these evolving standards to ensure they meet their needs.

CMS could play an important role in setting minimum standards for interoperability and defining information necessary to make the appropriate treatment choices. These standards would allow development of tools that could streamline prior authorization and other utilization management processes.

In its November 2018 *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*, the Office of the National Coordinator for Health IT (ONC) notes that prior authorization processes suffer from a lack of standardization and common approaches and that HHS can play a role in helping to evaluate and address process and clinical workflow factors contributing to the burden associated with prior authorization. ONC recommends that HHS work closely with standards development organizations, commercial payers, and others to support coordination of multi-stakeholder efforts to advance new standard approaches supporting prior authorization. Through one such existing effort, a private sector initiative led by the standards development organization Health Level 7 (HL7), Medicare fee-for-service is working with several other payers, EHR vendors, providers, and ONC to help find ways to reduce provider burden related to prior authorization requirements and related documentation requirements. ASCO is supportive of these and similar efforts and offers its assistance in providing the oncology community perspective.

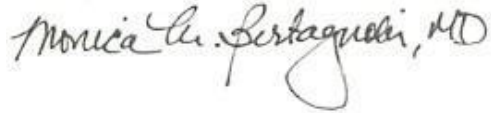
⁴ Winkfield, KM, Phillips, JK, Halpern, MT, et al: Addressing Financial Barriers to Patient Participation in Clinical Trials: ASCO Policy Statement, *J Clin Oncol* 36:3331-3339, 2018. Available at: <http://ascopubs.org/doi/pdf/10.1200/JCO.18.01132>.

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Thank you for the opportunity to provide comments on new policies for the regulation of Medicare Advantage and Medicare Part D prescription drug coverage. Please contact Sybil Green at Sybil.Green@asco.org or 571-483-1620 with any questions.

Sincerely,

A handwritten signature in black ink that reads "Monica M. Bertagnolli, MD". The signature is written in a cursive style with a large, looped "M" at the end.

Monica M. Bertagnolli, MD, FACS, FASCO
President, American Society of Clinical Oncology