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January 16, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave, S.W.
Washington, DC 20201

Re: CMS-4182-P. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.

Dear Administrator Verma:

The American Society of Clinical Oncology (ASCO) is pleased to provide comment on the proposed rulemaking revisions to the Medicare Prescription Drug Benefit Program (Part D) for 2019, which was published by CMS in the Federal Register on November 28, 2017. ASCO is the national organization representing over 42,000 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.

Traditionally, cancer therapies were provided intravenously and reimbursed by Medicare through the Part B benefit. Many anticancer drugs are still administered via infusion, but recent scientific developments and advances have increased the proportion of orally administered anticancer drugs.

This rise in orally administered cancer therapies has created new challenges in securing patient access to the most appropriate treatment at the most appropriate time for their diagnosis and unique clinical condition. We wish to 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 and other cancer stakeholders have supported legislation at the state and federal levels to provide oral chemotherapy on financial terms that are analogous to traditional IV therapies. Despite these efforts there are still gaps in patient access that can be attributed in large part to utilization management and business practices of PBMs and Part D plan sponsors.

ASCO members have significant concerns about the unnecessary administrative burdens imposed by the existing policies of PBMs. Cancer care decisions should be guided by the medical team and the patient. However there is increasing interference by PBMs through non-medical switching, delays in prior approval requests and deliveries of incorrect prescriptions. PBMs have also made medical decisions that impact patient care without the approval of physicians regarding dosage amounts; a choice that should never be made independently by an administrative intermediary. ASCO urges CMS to go beyond the transparency concerns that have been outlined in the RFI and examine the impact of PBM business practices on patient care and outcomes. As providers are being increasingly held accountable for quality outcomes, it is important to understand the impact of actions being taken by PBMs, which that affect patients in ways beyond a provider's control.

There are several approaches that Medicare can take to promote more robust access to cancer therapies. One promising approach is the implementation of high-value clinical pathways as a mechanism to promote the appropriate selection of anti-cancer therapies. ASCO is a strong supporter of high-value clinical pathways because they promote access to the right drug, for the right patient at the right time. We urge CMS to explore mechanisms to promote the use of high-value clinical pathways by Part D plan sponsors and PBMs.

Our comments on the provisions in this proposed rule follow below.

ASCO appreciates the Agency's interest in evaluating the financial relationships between Part D stakeholders. As CMS weighs new policies it is imperative to also ways to guard against instances where financial toxicity will impede patient access for cancer patients to life-saving and life-extending drugs.

The Part D benefit was established to promote robust access to prescription drug therapies at an affordable cost to Part D enrollees. We applaud the Agency's decision to issue an RFI seeking comment on new strategies to meet that objective and continue to promote patient access to cancer therapies by evaluating the financial relationships between Part D plans, pharmacy benefit managers, manufacturers, and pharmacies. It is critical that the Agency recognizes the connection between high out of pocket costs, access, and quality. Rising out-of-pocket costs create the potential for non-adherence and raise the risk that cancer patients will abandon life-saving and life-extending treatments altogether. Financial toxicity remains a major risk in cancer treatment and CMS should aggressively work to ensure access to life-saving treatment. Cancer patients should be protected from policies that may increase out-of-pocket costs in a manner that undermines the rationale for maintaining insurance coverage to offset potentially catastrophic costs. ASCO looks forward to providing formal comment on any policies the Agency may propose at a later date.

CMS should clarify the "any willing pharmacy requirements" to explicitly recognize in-office physician dispensing and physician-owned pharmacies as being capable of meeting the standard terms and conditions for network participation.

The "any willing pharmacy" protection is a crucial protection that ensures Part D enrollees have robust access to pharmacy providers of their choice. For cancer patients, this may include a pharmacy or physician's office dispensing oral oncology drugs. Any limitations on the ability of a pharmacy or dispensing physician to enroll in a network could impede patient access and jeopardize care. One practice of PBMs is to limit participation only to pharmacies that fall squarely within the definition of a certain pharmacy type (retail, mail order, long-term care/institutional etc.). This practice undermines the breadth of pharmacy networks and may cause delays or impede patient access to cancer therapies.

Community oncology practices and hospital-based practices often have their own on-site pharmacies or offer on-site dispensing of chemotherapy and supportive drugs that allow cancer patients to access all needed pharmacy services in one location at one time. These services include important follow-up, and the ability to make necessary changes to therapy without additional delays. We urge CMS to ensure that these pharmacies are able to participate in Part D networks without significant and onerous burdens by ensuring these pharmacies are deemed "willing" to participate in Part D networks where they meet the plan's standard terms and conditions.

ASCO supports the Agency's efforts to eliminate arbitrary barriers erected by Part D Plan Sponsors and PBMs intended to limit the number and types of pharmacies that can dispense drugs for certain conditions, including oral cancer therapies.

Oral anticancer drugs are complex and often require special handling or patient education prior to being dispensed. We appreciate that CMS and Part D plan sponsors each have vested interests in promoting high-quality pharmacy practices for Part D beneficiaries. However, counterproductive or ineffective accreditation or certification processes as part of the network credentialing process should be closely monitored by the Agency. These contractual standards may act as an artifice to exclude participation in Part D plans by pharmacies that are both willing and able to meet standard terms and conditions to participate in the Part D network.

The Agency's statement establishing an expectation that plans should not restrict pharmacies from dispensing certain drugs or drug types, absent FDA dispensing requirements or state law, correctly establishes that capable pharmacies should not be subject to arbitrary payer requirement to provide the services they are qualified to provide to Part D enrollees. ASCO strongly supports the Agency's efforts to eliminate duplicative, onerous and unnecessary accreditation standards, especially those that are plan specific or PBM specific as a condition of participation in a PBM

network. Eliminating these burdens will promote patient access to Part D drugs in a more expedient fashion.

CMS should exempt cancer drug therapies from specialty tiers because specialty tier placement imposes high cost-sharing burdens that target cancer patients. Given the limited treatment options that cancer patient possesses it is fundamentally unfair and counterproductive to include cancer drug therapies on a specialty tier.

In an effort to limit or discourage use, payers are increasingly placing cancer therapies on the "specialty tier" of their formularies. Placing a drug on a specialty tier shifts a large portion of the cost of care from the payer to the patient, resulting in significant adverse impacts on patient finances, which contributes to medical bankruptcies and disproportionately affects low-income populations.

High coinsurance rates related to specialty tier designation undermine the primary purpose of health insurance— causing cancer patients to face significant financial burdens or to forgo access to life-extending and life-saving drugs. Specialty tiers include drugs that are high cost, molecularly complex, or require special handling, administration and patient education. Under certain Part D plan designs, drugs placed on specialty tiers can result in coinsurance of up to 33% of the drug's cost. Contrary to the Agency's assessment, specialty tier placement does not enhance access to high-cost drugs. Instead, it limits access by conditioning treatment on the enrollee's ability to bear higher out-of-pocket costs. Anti-cancer drugs on a specialty tier may provide the best—or only—treatment option for individual patients. ASCO urges CMS to exempt anticancer drugs from placement on specialty tiers.

CMS should finalize the inclusion of individuals with a cancer diagnosis within the definition of an "exempted beneficiary" for the purposes of utilization management of opioids as directed by the *Comprehensive Addiction and Recovery Act* (CARA).

ASCO is a strong supporter of the policies within the *Comprehensive Addiction and Recovery Act* intended to address the opioid addiction epidemic. We applaud the Agency's dedication to implementing policies to prevent and mitigate the opioid epidemic's consequences throughout the country. As CMS continues implementing CARA's directives, the Agency must consider the unique needs of specific populations to prevent any unintended gaps in patient access to medically necessary pain medication, including the cancer patient population.

ASCO supports the Agency's proposal that exempts cancer patients from CARA's new drug management program for at-risk beneficiaries. The proposed policy acknowledges that oncologists are specially trained to help patients cope with pain that cancer patients may encounter throughout their cancer treatments. Prescription medications with addictive potential are widely used in palliative care and to treat pain associated with cancer and both chemotherapy and radiation therapy treatments. The Agency's decision to exempt cancer patients from the

program recognizes their unique needs and alleviates efforts impede immediate and timely access to medically necessary pain relief during all stages of treatment.

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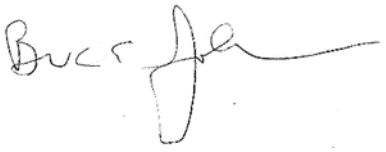
Thank you for the opportunity to provide comment on the 2019 Medicare Part D proposed rule. Please contact Sybil Green at Sybil.Green@asco.org with questions.

Sincerely,



Bruce Johnson, MD, FASCO

President, American Society of Clinical Oncology