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July 25, 2019

The Honorable Chuck Grassley
Chair, Senate Committee on Finance
U.S. Senate
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member, Senate Committee on Finance
U.S. Senate
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden,

The American Society of Clinical Oncology (ASCO) is pleased to provide comments on the committee's bipartisan prescription drug pricing proposal, "The Prescription Drug Pricing Reduction Act (PDPRA)." The accessibility and affordability of prescription drugs for patients with cancer is a high priority for ASCO.

ASCO is the national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are committed to ensuring that evidence-based practices for the treatment of cancer are available to all Americans.

We commend the committee for taking important steps to address the high cost of prescription drugs. We are supportive of many of the provisions included in the mark, including efforts to encourage the use of biosimilars and generics, increase transparency, and address drug waste. ASCO is concerned, however, that certain provisions may have unintended consequences for patients with cancer and the oncologists who treat them. Sections we particularly wish to call attention to follow:

Section 102: Inclusion of Value of Coupons in Determination of Average Sales Price for Drugs, biologicals, and biosimilars under Medicare Part B

ASCO has deep concerns about the potential for unintended consequences stemming from this provision. As expressed in our Affordability Statement, ASCO believes that cost-containment strategies for prescription drugs should not limit the ability of patients to receive access to appropriate care, or for providers to prescribe such care. ASCO is deeply concerned about any additional financial burden facing cancer patients if coupons were less accessible and would be opposed to any policy that effectively reduced their ability to utilize all available financial assistance.

Making a world of difference in cancer care

In addition, there is a very real possibility that this provision could result in additional financial pressures and significant disruption to oncology practices across the country by causing “underwater” drugs, meaning that the practice pays more for the drug than they are reimbursed by Medicare if it does not result in lower list prices as intended. This could exacerbate patient access issues and increase costs because practices in this situation may have to shift chemotherapy administration services to hospital settings. Physicians do not control the launch price of drugs and should not be held accountable for it.

Sections 105: Temporary Increase in Medicare Part B Payment for Biosimilar Biological Products

To date, the Food and Drug Administration (FDA) has approved nine biosimilars to treat cancer or as a supportive care agent in the cancer setting. Additionally, oncology biologic products with patents scheduled to expire by 2020 total global annual spending of more than \$20 billion. We appreciate the Committee’s commitment to increasing development of biosimilars. In cancer, prescribing decisions are made based on the best evidence that the treatment is right for an individual patient. Where efficacy and toxicity are the same, physicians should choose the lowest cost option for their patients.

Section 108: Requiring Manufacturers of Certain Single-dose Vial Drugs Payable under Part B of the Medicare Program to Provide Refunds with Respect to Discarded Amounts of Such Drugs

ASCO shares the Committee’s concerns about drug waste and is pleased to see the provision that extends the use of the JW modifier to better identify sources and cost of waste related to drugs in Part B. We encourage Congress to work with CMS to similarly use the JW modifier and its data in Part D and to make the data available to the public, for broader impact. While ASCO believes this provision may be an effective way to reduce or eliminate drug waste, we would oppose any provision that creates intrusive, complicated, or burdensome auditing practices for providers and their practices. ASCO would strongly oppose any proposal that would financially penalize a provider based on the amount of unused drug that remains in a vial after a patient has been appropriately treated.

Section 110: Establishment of Maximum Add-on Payment for Drugs, biologicals, and biosimilars

The existing system of payment for in-office administered drugs, such as chemotherapy, was created to ensure that the costs to procure, store, handle, and dispose of these treatments did not hinder access and availability. It is important to note that the full Average Sales Price (ASP) plus 6% in statute is not currently being provided to practices because a reduction due to sequestration has brought that number down to ASP plus 4.3%. As the Committee considers changes to that system, including the establishment of a maximum add-on payment, it is important that the cap amount be sufficient to cover costs and updated frequently enough to keep up with a rapidly changing practice environment.

Section 111: Treatment of Drug Administration Services Furnished by an Off-Campus Outpatient Department of a Provider

Rather than reducing resources devoted to cancer care that are determined by picking the lowest cost among care settings, ASCO encourages Congress and CMS to work on reforms that support the full scope of services required by patients with cancer and provide adequate resources to providers for the actual cost of providing oncology care to Medicare beneficiaries.

Section 121: Medicare Part D Benefit Redesign

A 2018 study titled “Financial Toxicity in Adults with Cancer: Adverse Outcomes and Noncompliance” published in the *Journal of Oncology Practice* revealed that patients with cancer who reported financial toxicity were less likely to fill their medications, attend office visits, and undergo recommended medical tests. Financial toxicity can add significant stress for a patient battling cancer and increase a patient’s likelihood to abandon treatment or become noncompliant with his or her treatment plan.

ASCO shares the Committees’ concern about the increasing out of pocket costs for Medicare beneficiaries and supports proposals to cap their Part D out of pocket costs. We are still examining the full details of the policy changes in this provision and their impact on patients with cancer and will be back in touch with the Committee with additional feedback.

Section 123: Public Disclosure of Drug Discounts and Other PBM Provisions

We hear serious concerns from our members about the negative effects of certain pharmacy benefit manager (PBM) practices on patients and the cancer care system. ASCO applauds efforts to improve transparency in the pharmacy benefit managers (PBM) market, particularly with respect to spread pricing and inappropriate/non-transparent direct and indirect remuneration (DIR) fees. ASCO has long maintained that the misapplication of non-oncology performance metrics, resulting in claw backs to pharmacies, has no basis in statute, while being highly profitable for PBMs.

Additionally, ASCO appreciates proposed transparency between insurers and dispensing pharmacies, but we remain concerned about the need for CMS to enforce its “Any Willing Provider” provision in Medicare Part D, to prevent PBMs from excluding qualified in-office dispensing or provider-led pharmacies from its networks.

Section 124: Public Disclosure of Direct and Indirect Remuneration Review and Audit Results

We support the committee’s efforts to increase transparency around direct and indirect remuneration fees.

Section 125: Increasing Use of Real-Time Benefit Tools to Lower Beneficiary Costs

Under this provision, Part D insurers would provide a “real-time benefit tool (RTBT)” that enables electronic transmission of formulary and benefit information to each enrollee’s prescribing clinician, using technology that integrates with clinicians’ electronic prescribing and EHR systems. We support the requirement of the “real-time” nature of these electronic transactions to include enrollee-specific benefit information and any prior authorization requirements and appreciate the requirement for integration of RTBTs into qualified EHRs as this could streamline workflow and increase efficiencies. We also support the awarding of credit under MIPS to physicians using RTBT as the use of this tool would be reflective of a practice activity that promotes beneficiary engagement and patient education.

Section 201: Medicaid Pharmacy and Therapeutics Committee Improvements

ASCO supports this provision, provided that these new requirements specify that Pharmacy and Therapeutics committees should include full and meaningful participation by oncology specialists. A lack of oncology specialists on a P&T committee can lead to mistakes and omissions for cutting-edge and complex cancer medications, leading to inferior care for cancer patients.

ASCO appreciates the committee's consideration of our comments. If you have questions on any issue involving the care of individuals with cancer, please contact Jennifer Brunelle at Jennifer.Brunelle@asco.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Howard A. Burriss III". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Howard A. "Skip" Burriss III, MD, FACP, FASCO
President, American Society of Clinical Oncology