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**Via Electronic Submission**

July 16, 2018

The Honorable Alex Azar  
Secretary  
Department of Health and Human Services  
200 Independence Ave. SW, Room 600E  
Washington, DC 20201

**RE: Request for Information HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs**

Dear Secretary Azar:

I am pleased to submit these comments on behalf of the American Society of Clinical Oncology ("ASCO") in response to the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs on Drug Pricing, and Request for Information (RFI) released in May 2018.

ASCO is the national organization representing nearly 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.

We appreciate the opportunity to offer input on strategies for ensuring equitable access to high-quality, high-value cancer care at a lower cost for patients who depend on existing and innovative life-saving and life-prolonging therapies. In recent years, there has been tremendous progress in the development of new classes of drugs that have greatly improved outcomes for patients with certain cancers. However, high drug prices are a prominent factor in eroding access to care for patients, particularly many cancer patients.

The cost of cancer drugs is rising faster than other parts of the cancer care delivery system, and significantly changing the way care is accessed, delivered and paid for.<sup>1</sup> First, many patients are facing high out-of-pocket costs and may choose to abandon treatment, which significantly impacts overall outcomes. Second, the quality of care provided to patients is threatened as oncology practices are challenged by increasing administrative burdens, regulatory requirements, and utilization management restrictions. Third, payor developed payment policies in both the public and private sectors have not kept pace with exceptionally high prices of new drugs entering the marketplace. Finally, the lack of transparency as to how the price of drugs is set continues to complicate the pursuit of adequate solutions. These dynamics are placing patients and physicians in financially challenging situations which impede care and are becoming unsustainable.

Concern about the impact of high drug prices on patients with cancer prompted ASCO to develop resources for patients and physicians, including:

- Doctor-approved patient Information on “Managing the Cost of Cancer Care: Practical Guidance for Patients and Families”<sup>2</sup>
- A value framework to assess the incremental benefit of new therapies
- A new approach to physician payment in the Patient-Centered Oncology Payment Model (PCOP)
- A robust performance measurement and quality improvement system, through The Quality Oncology Practice Initiative (QOPI)
- The American Society of Clinical Oncology Position Statement on Addressing the Affordability of Cancer Drugs

Today’s reality is that physician payment for patient services and reimbursement for drugs used to treat cancer together form the total resources available for practices to treat patients. Because of the way the Medicare payment system developed, drug reimbursement currently subsidizes longstanding gaps in payment for services that are not reimbursed but that cancer patients expect and need—oncologists and other oncology professionals spend extensive uncompensated time developing treatment plans, performing patient education and counseling, providing coordinated patient care, providing access to social workers, psychologists, patient navigators, triage nurses, genetic counselors, and financial counselors.

Payment reform for oncology drugs cannot be separated from policy changes contemplated for the complex set of oncology services that are medically necessary for optimal patient outcomes. For example, the recently proposed rule for Medicare’s physician fee schedule would, if finalized, impose substantial cuts in reimbursement to medical oncologists in large

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<sup>1</sup> Promoting Value, Affordability, and Innovation in Cancer Drug Treatment, President’s Panel Report, [https://prescancerpanel.cancer.gov/report/drugvalue/pdf/PresCancerPanel\\_DrugValue\\_Mar2018.pdf](https://prescancerpanel.cancer.gov/report/drugvalue/pdf/PresCancerPanel_DrugValue_Mar2018.pdf), March 2018.

<sup>2</sup> American Society of Clinical Oncology, ASCO Answers, Managing the Cost of Cancer Care: Practical Guidance for Patients and Families, [https://www.cancer.net/sites/cancer.net/files/cost\\_of\\_care\\_booklet.pdf](https://www.cancer.net/sites/cancer.net/files/cost_of_care_booklet.pdf)

part because the proposal would reduce payments for the most complex patient visits under Medicare's evaluation and management codes. Policymakers should evaluate the overarching impacts of proposed changes on the oncology community rather than implementing changes in a piecemeal fashion. Stakeholders from various sectors have proposed solutions to the drug affordability dilemma, however, there is no consensus on any of the proposed initiatives, and many of these proposals still need to be further defined and tested before they are broadly implemented.

ASCO's position statement on drug affordability calls for policy solutions that address access, affordability, and innovation. The statement lays out broad principles encouraging consideration of policies that: 1) ensure patients have access to necessary treatments and do not suffer devastating financial hardship when receiving the care they need, 2) aligns reimbursement with providers' delivery of the right treatment at the right time to the right patients and 3) support innovation by manufacturers and the investment community particularly in high-risk research that leads to high-reward science delivering more than modest (incremental) advances. In the context of our previous efforts and comments, we offer the comments below on the Agency's specific requests for information:

### **I. Defining Value**

Value-based solutions that are patient-centered and evidence-driven should inform drug prices in the United States. ASCO and others in the oncology community have proposed methods, both to assess value and to place that value in the context of individual patient wishes and treatment goals. Value considerations in oncology must consider the potential impacts on length of life, quality of life, medical complications, and costs incurred by the medical system, patients, and society.

ASCO is prepared to collaborate with government officials, payers, and other stakeholders to tackle the complex task of defining and assessing value in oncology. The expertise of oncology professionals—the clinical experts—must play a central role in making important decisions about the value of drugs used in the care of patients with cancer. Although health care providers do not control the price of a drug, they can—and should—lead in assessing the value of drugs, therefore enabling physicians to be good custodians of the healthcare resources we have at our disposal.

### **II. Feedback on Proposals**

#### **Outcomes/Indication Based Pricing:**

**Indication-based and outcomes-based payment arrangements and rebates should only exist between CMS/payers and manufacturers, and such arrangements should not result in higher patient costs for patients or physicians.**

The RFI specifically proposes indication-based payments as one way to help reduce the

cost of drugs and outcomes-based arrangements are often proposed as a reimbursement construct. While these arrangements have been used in the private sector, it is unclear what their ultimate impact on drug prices would be. There are challenges in implementing indication-based and outcomes-based payment arrangements, such as the need for a widely accepted mechanism to determine value. For example, as new, effective immunotherapy drugs are becoming available, policymakers and payers may struggle to determine the most appropriate indication-based or outcomes-based payment levels when such a therapy is used to treat different types of cancer, such as lung cancer versus melanoma.

Securing cost reductions for oncology drugs through indication-based and outcomes-based pricing arrangements is further complicated by the fact that many cancer patients have a limited number of treatment options. In many situations, there is only one drug that provides an individual patient with the best chances of a favorable clinical outcome. Similarly, in a number of instances, individual cancer drugs are only approved by the Food and Drug Administration for one clinical indication. Measuring clinical outcomes for individual patients is further complicated by adverse outcomes, including death, which may or may not be related to a particular oncology treatment.

Cancer care is complex, and physicians should never be penalized for using the most appropriate treatment for an individual patient. CMS should build on its current investment in measure development, working with oncology experts to enhance the portfolio of outcome measures for oncology care. ASCO has responded to the recent funding announcement, and we encourage the Agency to expand such efforts.

#### **Long-term financing models:**

**CMS should not create excessive financial risk for oncology practices by reimbursing over extended periods or otherwise using long-term financing models.**

ASCO is concerned that the proposed long-term payment models would further jeopardize already strained patient access to cancer treatment and place an undue burden on oncology practices. As a practical matter, independent physician practices rely on prompt payment for the significant outlays associated with purchasing oncology drugs prior to administration to patients. The burden of purchasing drugs is already contributing to financial pressures that threaten the viability of independent oncology practices that provide critical points for patient access throughout rural and underserved areas of the United States. Any long-term financing model that further extends the payment period for community-based oncology practices will undermine the viability of these practices and exacerbate the trend toward consolidation of independent practices,

by hospital systems, which has been associated with increased costs for payers and patients.

This policy would exacerbate longstanding and ongoing financial challenges oncologists face in providing medically appropriate treatment for their patients. Many oncology practices are small businesses that cannot secure lines of credit necessary to carry the amount of debt that would arise in such a system. Even now, community oncology practices often experience situations in which a dozen or more medically necessary drugs are “underwater” (i.e., the Medicare reimbursement rate does not cover the drug’s acquisition cost.)

Oncology practices cannot bear the risk of acquiring and dispensing costly cancer drugs and then waiting years to be fully reimbursed. The financial burdens placed on community-based oncology practices are already driving more and more parenteral cancer therapy into hospital outpatient settings, which can be inconvenient for patients and is often associated with higher health care costs for patients and payers. If Medicare and Medicaid require assistance in financing the purchase of high-cost drugs over time for patients, the financial risk should not be passed on to patients, physicians, or physician practices. Instead, any long-term financial risk should be borne by the manufacturers.

#### **Part B Competitive Acquisition Program (CAP):**

**A new CAP program must be significantly redesigned to address concerns about patient care and administrative burdens that arose when CMS initially implemented the CAP program in 2006.**

The CAP program, which ran from 2006 – 2008 was complex and problematic for both vendors and oncology practices. Ultimately, it was suspended by CMS due to lack of vendor competition, lack of physician participation and limited cost savings. ASCO believes that—for the CAP program to be attractive to physicians and effective at improving value by lowering the cost of drugs without undermining quality of care—significant revisions must occur.

Given the nature of cancer therapy, any revised program must pose fewer administrative burdens, allow greater flexibility for changes in dosing or date of administration, allow greater flexibility for use of CAP drugs at multiple offices in one practice, must offer patients help accessing co-pay assistance, and provide more patient protections around cost-sharing. In particular, we urge CMS to include the following elements in an attempt to revive the CAP program.

*Make the program genuinely voluntary and preserve the current structure while offering physicians the option of the CAP program. Some small practices could benefit from volume-based purchases and discounts in the CAP program, while some large, multispecialty practices may be more effective at lowering prices through directly purchasing drugs in the current ASP-based system. As previously mentioned, providers choosing not to participate in CAP should not be penalized.*

*Provide supplemental payments to support complex care coordination and management for cancer patients.* Supplemental payments are needed to provide fair and flexible payment to support the full scope of services needed to provide high-quality oncology care and promote patient choice and autonomy. This includes reimbursement for otherwise unreimbursed costs associated with the administration of anticancer drug regimens, including special handling and storage required for hazardous drugs.

*Permit flexibility that reflects the modern practice of oncology.* There needs to be flexibility in allowing for variation in orders that may occur on the day of treatment, as well as to permit the use of CAP-acquired drugs at multiple office locations.

*Availability of multiple national and regional vendors.* Oncology practices should be able to choose from multiple vendors to ensure competition exists for both pricing and service. Vendors must deliver high-level service to ensure that patients receive timely access to the most appropriate anticancer regimens. Vendor qualifications should include appropriate safety and quality standards. The program should also allow practices able to qualify as a vendor to bid on drugs and purchase drugs directly for its own use.

*Address patient care issues.* Robust and comprehensive patient protections must be included. Vendors must not interrupt patient access to medically necessary treatments or otherwise delay shipping due to delayed or delinquent co-pay issues. Vendors should be required to help patients find assistance or consider alternative payment arrangements if a patient cannot meet his or her cost-sharing responsibilities. The vendors should bear the risk of non-payment of patient copayments in a manner that does not penalize the treating physician and that does not interrupt patient care.

*Utilization management policies should not be tied to negotiated discounts.* Some pharmacy benefit managers (PBMs) may be eligible to act as vendors in the new CAP program because they currently serve as group purchasing organizations (GPOs). However, many PBMs receive the benefit of certain rebates and discounts in exchange for utilization management policies like step-therapy and tiered formulary placement, which delay or impede patient access to care. ASCO opposes practices such as step therapy, which can delay or otherwise compromise timely access to the treatment most appropriate for the patient's disease and individual circumstances.

### **Moving Drugs from Part B to D:**

#### **ASCO opposes moving chemotherapy and supportive care drugs from Medicare Part B to Part D.**

The current reimbursement system can impose different burdens—and costs—on patients and physicians, depending on whether drugs are intravenous (normally offered under Part B and administered incident to physician services), or oral (provided under Part D, and typically dispensed by a retail or specialty pharmacy). For certain drugs—or classes of drugs—used in

cancer treatment, the RFI proposes selective categorization into Part B or Part D, depending on whether the move from Part B to D would achieve savings. This significant restructuring should not be undertaken without careful consideration of the impact it would have on patients.

A primary concern is the potential for patients to experience higher out-of-pocket costs and/or loss of coverage. There are approximately 9 million Part B beneficiaries who do not have Part D prescription drug coverage. Transitioning coverage to Part D would dramatically undermine coverage for these beneficiaries. Additionally, co-insurance and out-of-pocket costs for anti-cancer therapies provided under Medicare Part D plans were more than 30 percent higher than costs for therapies covered in Part B: \$3,200 compared to \$2,400.<sup>3</sup> Such a differential could be devastating for cancer patients who are already financially strained. Finally, most Part B beneficiaries (80%) have some form of supplemental coverage through Medigap plans to assist with cost sharing. Such supplemental coverage enables millions of Medicare beneficiaries to share the 20 percent copayments, and as a result, only modest changes in monthly Medigap premiums are attributable to oncology drugs. However, these supplemental policies would not assist with Part D cost sharing. Moving cancer drugs to Part D would significantly exacerbate problems with patient affordability of cancer drugs and place the entire burden of the copayment/coinsurance for cancer drugs on beneficiaries with cancer.

Another concern with shifting oncology drugs to Medicare Part D is magnification of growing issues related to pharmacy benefit managers' (PBM) impact on patient access and affordability. ASCO members are reporting delays in treatment, medication switching without physician notification and unnecessary administrative burdens imposed by the existing policies of PBMs. These practices are not present in Medicare Part B.

Finally, there are differing views on whether moving Part B drugs to Part D would result in savings (Acumen, Avalere and HHS studies all vary on the outcome of the move; some raising prices and some lowering prices).<sup>4,5</sup>

### **Site Neutrality:**

**ASCO opposes removing any resources from the cancer care delivery system, regardless of setting, to reconcile differences in payment in different care settings.**

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<sup>3</sup> Matt Brow and Richard Kane. "Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D." May 21, 2018. [http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d?utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=newsletter\\_axiosvitals&stream=top](http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top).

<sup>4</sup> Marrufo, Grecia M, Emil Rusev, Kristy Piccinini, Elizabeth Coombs, Ken Ueda, and Erica Schechter. 2011. "Estimating the Effects of Consolidating Drugs under Part D or Part B." Burlingame, CA: Acumen, LLC, [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Acumen\\_B\\_to\\_D\\_Final\\_Report\\_2011.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Acumen_B_to_D_Final_Report_2011.pdf)

<sup>5</sup> Department of Health and Human Services Report to Congress: Transitioning Medicare Part B Covered Drugs to Part D, 2005, [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/RtC\\_PtbtoPtD\\_2005\\_4.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/RtC_PtbtoPtD_2005_4.pdf)

ASCO agrees that the current systems for reimbursement of outpatient cancer care under Medicare are flawed and outdated and should be reformed. In fact, ASCO's 2015 statement on site neutrality calls for comprehensive payment reform, rather than the piecemeal approach inherent to "site neutral" policies that do not address underlying flaws in the payment system—and could jeopardize patient outcomes by reducing resources in either care setting. Instead of using site neutrality as a justification for cutting reimbursement levels in a piecemeal fashion, policymakers should recognize that the current reimbursement systems for oncology care fail to recognize many multidisciplinary services that are critical to providing high-quality, high-value cancer care.

The two outpatient systems were designed separately and have evolved independently. The payment methodology established under the Medicare Physician Fee Schedule—which considers relative value units based on survey data and estimates of required resources—and the methodology established under the hospital outpatient prospective payment system—which considers charge data submitted by hospitals—are based on different assumptions, calculations, and conversion factors. There is not a logical reason for concluding reductions are warranted in one system, simply because of payment and market dynamics in the other setting. By removing resources from either setting, policymakers risk exacerbating payment issues and disparities in both.

Policymakers should evaluate oncology reimbursement in a comprehensive manner to ensure that fair and adequate payments are made for all such medically necessary oncology services.<sup>6</sup> By providing practices flexibility—and the resources needed for comprehensive patient management, including avoidance of unplanned ER visits and hospitalizations, the Medicare program would promote value by improving the quality of care and reducing costs by decreasing unplanned acute care and improving the management of end-of-life care.

### **The 340B Drug Discount Program:**

The 340B Drug Discount Program has a significant effect on the delivery of oncology services in the United States, especially given the critical role of drug therapies in the treatment of cancer. ASCO's 2014 "Policy Statement on the 340B Drug Pricing Program"<sup>7</sup> addressed fundamental issues regarding the intent, size, and oversight of the 340B program and called for reforms to bring the program into alignment with its original intent, which is to ensure access to high-quality care for underserved and vulnerable individuals.

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<sup>6</sup> American Society of Clinical Oncology Policy Statement on Site-Neutral Payments in Oncology, *Journal of Clinical Oncology* 34, no. 3 (January 20, 2016) 277-279, <http://ascopubs.org/doi/abs/10.1200/jco.2015.64.0615>

<sup>7</sup> American Society of Clinical Oncology, Policy Statement on the 340B Drug Pricing Program by the American Society of Clinical Oncology 4 *Journal of Oncology Practice* 259-259 (2014) *available at* <http://ascopubs.org/doi/pdf/10.1200/JOP.2014.001432>



**Policymakers should replace the Disproportionate Share Hospital (DSH) adjustment percentage as a program eligibility metric for hospitals with a metric that more appropriately reflects the original intent of the 340B program.**

The 340B statute creates program eligibility for several types of hospitals based on their DSH adjustment. The majority of program growth has been observed in hospitals that have a DSH percentage of at least 11.75% and meet other enumerated eligibility criteria to obtain 340B eligibility. Using the DSH adjustment as a measure of eligibility for the 340B program is flawed because it is based on inpatient data; the 340B program only provides discounts for drugs used in the outpatient setting. This creates a fundamental disconnect between how hospitals obtain 340B eligibility and the services that the increased 340B resources are intended to promote. Both the Affordable Care Act and other Medicaid expansions have contributed to rising DSH adjustment percentages and, consequently, increased 340B hospital eligibility (because an increase in the overall portion of Medicaid inpatient days will raise an institution's DSH adjustment percentage).

ASCO supports removing the DSH adjustment percentage as an eligibility measure for hospitals in the 340B program. New 340B hospital eligibility measures are needed to better link program eligibility with the program's intent. Metrics should be objective, universal, and verifiable rather than applicable only to hospital settings. Policymakers should focus on metrics that align program eligibility with the care provided by the institution to indigent and underserved individuals. Doing so will better position the program to serve the patient populations originally intended to benefit. Alternative eligibility measures could be calculated by analyzing the amount of charity care provided by hospitals in the outpatient setting. Regardless of the metric, eligibility should be designed to qualify entities based on the amount of care delivered to underserved populations in outpatient settings. Such criteria should promote participation by practices of all sizes in all settings, should be standardized and applied in a uniform fashion, and should be verifiable to ensure that program integrity is protected. ASCO is prepared and ready to assist Congress and the Administration in developing and implementing policies to better reflect the original intent of the 340B program in this area.

**The 340B program should be refined to recognize, as eligible providers, standalone community oncology practices with demonstrated records of providing cancer care to uninsured, underinsured and indigent patients to secure patient access to cancer care services.**

Community-based oncology practices form the backbone of cancer care in many rural and underserved areas by serving as the sole point of access for oncology services. Community oncology practices are vital outlets for access to high-quality and cost-efficient oncology services for cancer patients from all walks of life. These practices regularly engage in the provision of care to indigent, underserved and uninsured individuals at a financial loss, yet do so without the benefit of 340B discounts enjoyed by oncology providers in other settings of care.

ASCO supports the inclusion of community oncology practices, with a demonstrated commitment to serving uninsured, underinsured and indigent patients, in the 340B program to promote increased access for these individuals. A dedicated group of ASCO volunteers is working to develop a revised eligibility formula, which appropriately captures the level of outpatient charity care provided by hospitals, as well as standalone community practices. The details of these recommendations can be shared with the agency in the near future.

#### **Increasing Competition and FDA Initiatives:**

**ASCO supports initiatives that would facilitate the development of new treatments for cancer patients. We also encourage policies that speed patient access to lower cost generics and biosimilars.**

ASCO applauds HHS efforts to enable the research and innovation that lead to more effective therapy for patients with cancer. Policies that allow restrictions on distribution of lower cost generics and biosimilars, including the extension of market exclusivity periods, data exclusivity, product hopping, evergreening and pay for delay impede access and result in overall higher costs to patients and the system and should be eliminated.

#### **III. The Solution is a Value-Based System That Protects the Interests of Patients**

The most effective means of managing limited health care resources is through a value-based health care delivery system. Such a system depends on a common definition and method for determining value, something that does not exist today. Addressing the drug price issue requires stakeholders across the healthcare system to acknowledge their role and participate in solutions. Oncologists do not control the price of the drugs, but oncologists do play important roles in determining how drugs are used to fight cancer. As such, oncologists should be integral to determining the value of drugs used in anticancer regimens, and oncologists should play an important role in any effort to design solutions. We embrace these challenges, and we look forward to continued collaboration with policymakers, payers, and other stakeholders.

The oncology community is well-positioned to develop guidance and clinical pathways that help minimize undesirable variability in the practice of medicine with respect to both drug and non-drug therapies and services. There are ways to implement policies that promote high-quality, cost-effective, and evidence-based practices without undermining the individual preferences of patients and the physician-patient relationship—such as by using evidence-based oncology pathways as described below. The oncology community is also well-positioned to help policymakers and other stakeholders identify instances in which there are two or more clinical options that offer relatively similar odds of success, especially for patients with common forms of cancer.

Unfortunately, in cancer care, there are many instances in which there is one superior clinical option for an individual patient. Oncologists are not well-positioned to offer cost-savings for patients when there is only one expensive drug therapy that is clinically superior to all others, and policymakers should avoid mechanisms that pressure or penalize physicians in such situations.

ASCO has consistently advocated for a reimbursement system that does not penalize physicians for providing the right care to the right patient at the right time. The ideal payment model is one in which physicians are incentivized to deliver the highest quality care available to every individual patient at all points in the disease process. As such, physicians should not be incentivized to prescribe a therapy based on any factor other than what is best for the patient. For this reason, ASCO has highlighted the important role high-quality oncology care pathways can play in measuring drug utilization, thereby helping to meet the collective goal of delivering high-quality care. In its previous response to CMMI's request for information on Direct Provider Contracting design, ASCO outlined ways to better support the full range of services needed for oncology care planning and management, reduce unwarranted variation and cost by promoting evidence-based care, and organize reimbursement so that it works for a variety of care settings.<sup>8</sup>

Studies have shown a link between pathway adherence and quality of care. Pathways have also been shown to ensure patient safety, primarily through the avoidance of preventable hospitalizations or emergency department visits, and through the judicious use of supportive therapy. More specifically, ASCO's "Criteria for High-Quality Clinical Pathways in Oncology" are based upon consideration of a treatment's efficacy, toxicity, and cost for any individual patient, and thus ongoing patient safety will be best ensured through the rigorous deeming process for evidence-based pathways and subsequent pathway updates.<sup>9</sup> To this end, ASCO has proposed the use of pathways as a mechanism for measuring cost and quality in alternative payment models. As currently envisioned, such a proposal could be constructed for use within the Oncology Care Model as well as in any other alternative payment system.

Private payers have already been utilizing clinical pathways in novel reimbursement models for oncology care. CMS can gain valuable lessons from payers that have had success in reducing costs while improving or maintaining quality of care. ASCO is working to bring details of this proposal to CMMI this summer.

As a practical solution for these complex problems, ASCO also offers its alternative payment model—the Patient-Centered Oncology Payment (PCOP) Model and combined with the integration of high-quality oncology pathways—as a comprehensive approach to deliver and

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<sup>8</sup> ASCO Response, Request for Information on Direct Provider Contracting Models, Submitted May 25, 2018, <https://www.asco.org/sites/new-www.asco.org/files/content-files/ASCO-DPC-RFI-Response.pdf>.

<sup>9</sup> RT Zon, et. al., American Society of Clinical Oncology, Criteria for High-Quality Clinical Pathways *Journal of Oncology Practice* 13, no. 3 (March 2017) 207-210. Retrieved from <http://dx.doi.org/10.1200/JOP.2016.019836>.

pay for high-quality, high-value cancer care. PCOP can help address the utilization of both drug and non-drug therapies and services. PCOP offers an innovative approach to payment, providing stable and predictable reimbursement while allowing each oncology practice to deploy staff and resources in the way best suited to their specific environment and patient population. Triage and clinical pathways are a key element in PCOP, assuring consistent delivery of evidence-based treatment, care coordination across the oncology care team, and effective management of symptoms. By providing practices flexibility—and the resources needed for comprehensive patient management (including avoidance of unplanned ER visits and hospitalizations)—the Medicare program would promote quality and control cost.


The pathways project could be a stand-alone demonstration effort—or be included as a component of a broader demonstration of the PCOP payment model. We note that PCOP is currently in testing with one commercial payer, and additional payers and employer groups have recently expressed interest. We have also seen initial success in similar voluntary oncology models that promote practice transformation, such as the Come Home oncology model that demonstrated better managed care at a lower cost. We attach to these comments ASCO's proposed payment model.

We strongly urge policymakers to expedite the adoption of voluntary, value-based reform for oncology focused on the concepts within ASCO's PCOP and pathways projects, and we are prepared to collaborate with the Innovation Center staff and others to help develop and operationalize such models.

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Thank you for the opportunity to provide comment on this important initiative. ASCO shares the Administration's concern about the rising cost of drugs, the ability of patients to access necessary treatment, and the adverse impacts of high drug prices on the overall healthcare system. The larger healthcare community—including providers, patient advocates, payers, hospitals, experts in health economics and health outcomes, representatives from the pharmaceutical and biotechnology industries, Members of Congress, and Administration policymakers—must actively participate in developing policy solutions to address the affordability of cancer drugs. The Administration is uniquely positioned to convene appropriate stakeholders, and ASCO stands ready to participate in real solutions. For additional information, please contact Sybil Green at [Sybil.Green@asco.org](mailto:Sybil.Green@asco.org).

Sincerely,

A handwritten signature in black ink that reads "Monica M. Bertagnolli, MD". The signature is written in a cursive style with a large, looping 'M' and 'B'.

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

# ATTACHMENT

## **The ASCO Patient Centered Oncology Payment Model**

### **Introduction**

The American Society of Clinical Oncology (ASCO) believes that well-designed payment systems that reflect the current realities of today's oncology practice are essential to ensuring access to high-quality cancer care for people with cancer. Furthermore, oncologists – as the professionals with primary responsibility for cancer patients' well-being – must be active participants in the development and piloting of new reimbursement models.

The ASCO Patient-Centered Oncology Payment (PCOP) model outlined in this document reflects a multi-year developmental effort, first initiated in 2013, that applies our members' clinical and oncology practice expertise to the dual challenges of ensuring high-quality patient care and controlling unnecessary healthcare expenditures. The model was developed by a dedicated ASCO volunteer work group of leading medical oncologists, seasoned practice administrators, and experts in physician payment and business analysis. The current model integrates extensive feedback from a wide range of stakeholders, including policymakers, public and private payers, healthcare providers, and patient advocates.

The PCOP model prioritizes the imperatives of patient choice and access to care; reduces unwarranted variation in care while respecting clinicians' expert judgment; and addresses long-standing gaps in reimbursement for patient services that are essential to high-quality care. By making physicians meaningfully accountable for the quality of care they provide – while appropriately limiting the financial risks to practices – the model will advance the goals of moving from a volume- to a value-based reimbursement system

### **Payment Model Overview**

The basic PCOP model provides supplemental, non-face to face visit-based payments to oncology practices to support diagnosis, treatment planning, and care management. Oncology practices would be able to bill payers for three new service codes:

1. New Patient Treatment Planning
2. Care Management during Treatment
3. Care Management during Active Monitoring

Practices would continue to be paid as they are today for services currently billable under the Medicare Physician Fee Schedule, including Evaluation & Management services, delivery of chemotherapy and immunotherapy, and drugs administered or provided to patients by the practice.

PCOP introduces two-sided risk in a way that engages eligible clinicians while not putting financial viability of physician practices at risk. It requires robust reporting of quality measures and treatment pathway compliance to ensure high quality care and optimal utilization of therapeutics.

### **Goals of the Model**

- Better support for services critical to high value, high quality care. Oncology practices would receive payment for care management, including management of toxicities and other supportive care that patients with cancer require and that avoid costly hospitalizations and emergency department visits. Flexibility to accommodate individual practice circumstances. Payments would be made in a way that allows practices the flexibility to organize care delivery in a way that most efficiently deploys staffing and other resources in their environment and, most important, according to unique needs of the patient. It also enhances quality without increasing financial burdens on patients.

### **Expected Participants**

All patients who have a breast, colorectal, or lung cancer diagnosis requiring chemotherapy or immunotherapy are eligible to participate in the PCOP model. ASCO has engaged a wide range of oncologists from across the country in the development of PCOP, indicating its broad support and their willingness to participate. Additionally, one practice and commercial payer have implemented PCOP, showing its viability. We expect participation from medical oncology practices at diverse practice sites, including small independent practices, wherever PCOP is available.

### **Implementation Strategy**

ASCO is the leading professional society representing nearly 45,000 professionals who conduct clinical research and care for people with cancer. Our membership is engaged and eager to participate in testing innovative models that lead to better care. We anticipate continuing revisions of both our reporting requirements as well as the details of our two-sided risk financial components to meet the needs of all constituents. The PCOP model positions eligible clinicians to move into monthly bundled payments for services upon demonstrating their ability to succeed in this care management and payment environment.

### **Scope of the Model**

The Patient Centered Oncology Payment model addresses unmet Medicare needs by enabling all medical oncology practices to deliver higher quality care at lower cost. This model offers medical oncology practices – independent, physician owned, healthcare system owned, academic, urban, rural, large, and small – the opportunity to participate in innovative approaches to cancer care delivery. ASCO's members have designed this model and many members, including large and small independent practices, have expressed interest in voluntary participation. This model provides a mechanism to share savings and adopts a two-sided risk that accounts for individual patient complexity with reliance on both the evidence and value based clinical oncology pathways. The model incorporates reasonable risk boundaries to limit the financial risk to physicians and practices and allows small practices to accept two-sided risk. The

shared savings portion of this model has been implemented by New Mexico Blue Cross since February 2016.

This model can be piloted on a finite set of voluntary practices and Medicare covered patients and then expanded to all types of practices when proven successful. Medicare recipients will benefit from care delivered according to evidence and value-based oncology pathways, assuring up-to-date best standard of care and affording flexibility for rapid adoption of effective new therapies. The model accounts for individual patient complexity, which allows all patients access to best care, regardless of practice size or location.

We anticipate a four percent reduction of Medicare expenditures by utilization of this model and have designed it for use by other public and commercial health care payment systems.

### **Quality and Cost**

Adherence to clinical pathways is a key metric for quality in this model. Full participation in shared savings will require concordance with clinical pathways at a specified threshold for qualifying patients. In addition, quality of care will be evaluated using clinical quality measures that are meaningful for oncology care and captured electronically based on ASCO's over 170 measures included in the Quality Oncology Practice Initiative (QOPI) and Choosing Wisely program. Patient experience outcomes will be measured using a validated, standardized tool. This model will accommodate adoption of new oncology-specific measures, including patient reported outcome (PRO) metrics as they become available following testing and validation.

Robust quality measures and appropriate use guidelines protect patients from both over- and underutilization. This model embraces clinical pathways as an effective way to reduce undesirable variations in drug utilization, ensuring delivery of high quality care and appropriate use of resources.

### **Payment Methodology**

Practices will receive additional PCOP payments that will be adjusted on pathway compliance and quality metric performance. Overall episode cost less PCOP payments and drugs will be compared to a risk adjusted benchmark with a positive shared saving distributed to the practice adjusted by quality metric performance and the remainder distributed to CMS. A negative cost outcome will be covered by the practice based on the defined risk corridors.

High-value oncology care pathways will be a central component of this proposed alternative payment model and successful implementation will require clear and transparent payment methodology to minimize administrative burden of both CMS and oncology providers. This model provides oncology practices with supplemental, non-visit-based payments (PCOP payments), which are adjusted depending on pathway adherence rate and other quality metrics.

In addition to receiving PCOP payments, providers will be reimbursed as they are today for services currently billable under the Medicare Physician Fee Schedule. These include evaluation and management services, infusions of chemotherapy, and drugs administered or provided to patients in the practice. Finally, practices will have both upside and downside risk in the form of shared savings amounts that will be calculated

based on expected Medicare Part A and Part B reimbursements, exclusive of physician-administered drugs, oral oncolytics, and PCOP payments.

As a result, like the Oncology Care Model (OCM), three distinct payments will be made to each participating practice: traditional fee-for-service Medicare Part B payments, PCOP payments, and shared savings payments (or penalties). Differences from the OCM include the requirement for high-quality pathway utilization, phase-specific PCOP payments, use of patient-level clinical data for risk adjustment, and exclusion of physician-administered drugs from shared savings calculations.

The PCOP model payments include four additional flexible payments in addition to existing payments for evaluation and management services, infusions of chemotherapy, testing and imaging, and other procedures and services currently billed and reimbursed by the payer as well as drugs provided and administered by the practice. The new additional payments are made during an episode of chemotherapy or immunotherapy care and include end of life care services provided during hospice management.

1. Payment for New Patient Treatment Planning
2. Payment for Care Management During Treatment
3. Payment for Care Management During Active Monitoring and End of Life Care

### **Proposed Pairing of Risk Adjustment and Clinical Pathways in PCOP**

As has been demonstrated by OCM, inclusion of utilization data allows for improvement of a risk adjustment model when clinical data is not available. In the case of prostate cancer, not only are expected expenditures higher in the castration-resistant cohort, oncologists may experience in their practice case-mixes skewed towards a higher risk population. By assessing utilization of castration-sensitive vs. castration-resistant drugs, CMS was able to improve the overall fit of the OCM prediction model and accounted for case-mix differences among provider specialties.

However, relying solely on utilization data presents a risk to integrity of the payment model. In the case of breast cancer, it is possible that a provider may administer chemotherapy when it is not indicated, the result of which would be an inappropriate adjustment of expected expenditures. For this reason, data points representing utilization should be used selectively in risk adjustment. The difference in PCOP and OCM is the lack of clinical information available in claims data and its considerable impact to the precision available in a risk adjustment model. We acknowledge CMS' efforts to enrich claims data with the OCM's clinical and staging data registry, but we are concerned that its time and resource requirements—for both Medicare and practices—limit its feasibility and sustainability.

Inclusion of clinical pathways as a quality measure provides benefits of certain utilization data as a proxy for clinical data, while mitigating the risk of inappropriate utilization. For example, if a provider inappropriately administers chemotherapy in breast cancer, that utilization pattern will be present in a poor pathways quality score. This allows us to confidently develop additional risk adjustment factors for PCOP.



Clinical pathway utilization compliance also eliminates the confounding factor of novel drug introduction into the cost calculation encountered by OCM.

Providers who participate in this demonstration will be required to adopt and utilize clinical treatment and triage pathways that conform to ASCO's guidelines for high-quality, evidence-based pathways. A deeming mechanism will need to be established (CMS or ASCO) to ensure high quality pathways are used in this demonstration. A process will be formalized wherein pathway vendors attest that their pathway offerings meet the ASCO defined criteria to be an Oncology Certified Pathway (OCP) and practices attest that they are utilizing pathways that have been deemed to satisfy these requirements. Practices must be QOPI-certified and see a minimum of 20 eligible patients per quarter to participate in the demonstration. Participating practices must document either concordance with an OCP or treatment off-pathway for all eligible patients. Patients for whom a pathway is not available will be not be included in the calculation of performance metrics or bonus payments for this demonstration. Participating practices must commit to an information-sharing agreement with CMS and routine audits for quality improvement.

Practices that achieve pathway adherence rate targets will receive a determined percentage of PCOP payments in the following quarter. A positive PCOP shared saving payment will be adjusted annually by quality metric performance.

### **Shared savings will be benchmarked against a risk-adjusted standard**

Observed costs will be calculated per practice in each performance period and will be equal to the sum of all Medicare Part A and Part B reimbursements, exclusive of physician-administered drugs, oral oncolytics, and PCOP payments. Expected costs (exclusive of physician administered drugs and oral oncolytics) will be risk-adjusted and calculated on a per-patient, per-episode level and will be aggregated across a practice to obtain the practice's total expected costs during that performance period. The start of an episode will be defined by a treatment decision requiring injectable or oral oncolytics, while the end of the episode will be defined by a subsequent new treatment decision; six months post treatment completion, hospice enrollment, or death. A performance period will span 12 months and will capture all episodes that are completed within the performance period. Episodes that are scheduled to last more than 12 months will have cost reporting every 12 months until completion of the episode.

Patient-level risk adjustment will be performed from both historical claims data and practice-specific clinical data once enough data is collected or obtained from another source, including disease stage, genomic markers, line of therapy, and therapy intent. The use of pathways allows CMS to capture this clinical data in a structured format from each practice. Risk adjustment will be determined by the specific pathway employed and potentially several other risks per pathway to be determined (example age, functional status) after an initial period of data collection or from other sources to determine outliers. Cost adjustments for pathway alterations for new therapies will be determined at the time of pathway alteration. Savings will be calculated as the difference between expected and observed costs and with positive savings shared equally between the Medicare program and the participating practice and losses governed by the risk corridors.

Downside risk of practice excessive costs will be governed by established risk corridors. A positive shared savings to the practice will be adjusted based on pathway compliance quality metric performance.

### **Value and Volume**

High value oncology care will be incentivized—and supported—in two ways. First, there are supplemental, monthly payments that better support the wide range of services needed by patients and families confronting cancer and its consequences. This support provides practice resources to either avoid negative side effects of treatment, or better manage them when they occur. Second, PCOP embeds use of diagnostic, treatment, and triage pathways that smooth unwarranted variation in care for diagnostics, treatment, emergency room visits, hospitalization, and promotes appropriate and timely transition back to primary care or end of life care. Monthly care management payments will be reduced if a practice does not meet targets of pathway compliance; positive shared savings will be adjusted in accordance with additional quality performance measures. Oncology practice team care is required during an episode of therapy or at end of life and the entire team will be guided by pathway compliance. Oncology pathway utilization and compliance has been shown to support delivery of high quality care while controlling cost.

### **Flexibility**

The PCOP model is based on oncology diagnostic, therapeutic, and triage pathways utilization. These pathways are available for all types of oncology practices to adopt, and many can be incorporated into the practice electronic health record. Effective utilization of a triage pathway requires adjustments of the practice team care and scheduling and is adaptable to all size practices. New therapeutic advances will be rapidly incorporated into the pathways and pathway compliance metrics will assure rapid and wide spread dissemination of new care into practice providing rapid access by Medicare beneficiaries.

### **Metrics**

Practices will be monitored and evaluated by pathway compliance, quality metrics, treatment plan and summary completion, patient experience results, and elimination of avoidable costs.

Pathway compliance (our model proposes 80% as an initial benchmark) will be monitored real time from pathway software. Quality metrics will be chosen from over 170 ASCO QOPI and Choosing Wisely measures and reported electronically through a Qualified Clinical Data Registry (QCDR), ASCO's QOPI QCDR. The quality set will be adjusted as new and meaningful measures (including patient reported outcomes) become available.

Treatment plans, including identified and delineated care responsibilities for extramural caregivers, must be completed and distributed to the patient and family and associated providers (primary care and other pertinent specialists) at the onset of treatment. Treatment summaries are to be completed and distributed to the patient and family and associated providers within 45 days of treatment completion. Patient experience results will be measured by a standard tool. Avoidable diagnostics and drugs will be monitored by pathway compliance using payer claims cost data. Avoidable

emergency room utilization and hospitalization costs will be measured by payer claims data and combined with pathway generated clinical data.

### **Integration and Care Coordination**

The PCOP model is dependent on the successful utilization of the oncology practice care team and clearly structured coordination with physicians and services from external caregivers when required. Components of the oncology practice care team include physicians, oncology nurses, pharmacy and practice support personnel performing scheduling, financial counseling, and referral services. The team will have standard operating procedures to effectively utilize the triage pathway system.

Each episode of care will require a care plan that clearly identifies and delineates care responsibilities to required extramural providers and services and is delivered to the appropriate extramural care teams. For example, difficult to control hypertension or hyperglycemia to be managed by primary care or other specialist and difficult pain management by a palliative care team.

Oncology practices should be able to provide the team care with existing personnel, with adjustments to team member functions and office service schedules.

### **Patient Choice**

Pathway compliance is not expected to be 100% (we are proposing an initial benchmark of 80%). This allows patients and physicians to design a care plan appropriate for individual patient characteristics and circumstances. The expectation for broad pathway compliance for all patients reduces variation of standard care that is cited as a contributing factor for health care disparities.

### **Patient Safety**

Pathway compliance with up to date pathway utilization protects patients from stinting of care. The practice cost evaluation utilizing individual patient risk adjustments by pathway allows practices to accept patients with all levels of complexity and preserves patient access to care.

Patients will be protected by real time electronic reporting of practice pathway compliance and quality data through the pathway software and electronic QCDR quality reporting (ASCO QCDR). Practices not achieving pathway compliance or quality standards will be required to demonstrate a corrective action plan or will be excluded from model participation. QOPI Certification, which is required, includes comprehensive safety standards. Onsite audits inspect practice policies and procedures to assure the environment is one in which the practice team delivers treatments safely and accurately.