The US Oncology Network

July 16, 2018

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

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

RE: Request for Information on US Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (HHS-OS-2018-0010)

Dear Secretary Azar,

On behalf of The US Oncology Network, which represents over 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to provide feedback on the policy proposals and questions included in "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" and the accompanying Request for Information (RFI).

The US Oncology Network ("The Network") is one of the nation's largest and most innovative networks of community-based oncology physicians, treating more than 850,000 cancer patients annually in more than 400 locations across 25 states. The Network unites over 1,400 like-minded physicians around a common vision of expanding patient access to the highest quality, most cost-effective integrated cancer care to help patients fight cancer, and win.

As community-based providers of complex cancer care, we appreciate the administration's efforts to improve the affordability of drugs and recognize many of the blueprint's proposals as positive steps. These include efforts that aim to increase transparency, reduce patient cost sharing, and mitigate the harmful effects of provider consolidation. However, we have concerns that some of the administration's proposals could limit patient access to cancer treatments and impede providers' ability to deliver patient-centered, appropriate care.

As the administration looks for ways to manage prescription drug costs, it is also important to acknowledge opportunities to improve upon strategies that are already working to hold down drug costs in the oncology space through value-based care models and utilization of treatment pathways. The US Oncology Network has fully embraced the move toward value-based care which is demonstrated by the participation of 16 of our practices in the Oncology Care Model (OCM). These practices have voluntarily accepted the challenge of managing all aspects of a cancer patient's care for a 6-month period including the overall cost of drugs. Network physicians also adhere to clinical Pathways which utilize regimens that demonstrate value over volume and reduce non evidence-based variability in treatment. This use of patient-specific, evidence-based treatment pathways is bolstered by the current Part B drug reimbursement structure, which provides physicians and patients the flexibility to select appropriate therapeutic options.

The Network will focus our comments on key provisions impacting community-based oncology providers and care for cancer patients. We have organized our comments by topic area to facilitate your review, beginning with areas of concern and followed by areas of support.

Proposal Areas of Concern for Patients and Providers

We begin by detailing below proposals that deserve urgent attention for their potential negative consequences for both patients and providers. We are particularly concerned by proposals that could implement formulary restrictions in cancer care which would reduce patient access to oncology drugs and limit provider prescribing autonomy.

Transitioning Select Part B Drugs into Part D

The Network urges extreme caution with the administration's proposal to move some drugs from coverage under Medicare Part B to coverage under Part D. This proposal would have profoundly negative effects for cancer patients. Moving drugs from Part B to the more restrictive Part D benefit could present numerous barriers for both providers and patients, including increased out-of-pocket costs, prior authorization and step therapy requirements, and variable benefits.

Shifting drugs to Part D could significantly increase out-of-pocket costs and decrease access for patients. An analysis from Avalere Health[1] finds that Medicare patients' out-of-pocket costs for new cancer therapies can vary substantially based on whether a drug is covered by Part B or Part D. In 2016, average out-of-pocket costs were about 33 percent higher for Part D-covered new cancer therapies ($3,200) than for those covered under Part B ($2,400). Among Part D beneficiaries who do not qualify for low-income cost-sharing subsidies (LIS), which includes about 72 percent of enrollees, average out-of-pocket costs were even higher on average, at $4,400. Cost-sharing differences between Parts B and D result from differing benefit designs and use of supplemental health coverage. Around 86 percent of Part B beneficiaries have supplemental coverage to pay for certain services and out-of-pocket costs, but supplemental coverage is not allowed under Part D. Of potentially greater concern, about 27 percent of current Part B beneficiaries do not have Part D coverage which raises questions regarding opportunity for these beneficiaries to purchase Part D plans in a timely manner, education outreach efforts and whether any beneficiaries would encounter financial barriers to obtaining a Part D plan.

In addition to cost sharing, the use of restrictive drug formularies in the Part D program could decrease access to cancer treatments by limiting the full breadth of available therapies. This is particularly problematic in oncology, where there are often not therapeutic alternatives for a patient. Decisions as to which therapy a patient receives should be based on physicians' assessments of clinical need, not Pharmaceutical Benefit Managers' (PBMs) efforts to save costs. Also, a cancer diagnosis is often unexpected and unplanned. Many cancer patients may not be aware of their condition and required medications when selecting a Part D plan during the open enrollment period. The current Part B system has significantly fewer barriers to obtaining therapies because it is not controlled by third party plans.

Operationally, this policy would also create billing and reimbursement challenges and require new business models and workarounds. For example, Part D plans typically contract with pharmacies who bill Part D plans and receive reimbursement directly. Part D plans do not contract with physicians, and there are many operational factors that would make it difficult for physicians to directly bill standalone Part D plans (PDPs) for both drugs and administration

[1] Avalere Health, "Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D," May 21, 2018.

fees. Therefore, a B to D policy could place the burden on patients to pay their physician up-front and submit a claim to their Part D plan for reimbursement. The current "buy and bill" system under Part B, in contrast, facilitates a direct reimbursement process between providers and Medicare that does not burden patients.

We believe this proposal to shift coverage of drugs from Part B to Part D results from a significant misconception regarding the realities of the reimbursement methodology for Part B drugs. It is an attempt to resolve a problem with the current payment methodology that we believe does not exist. This proposal would create new systems to address high costs associated with the "buy and bill" model, when in fact providers do not inappropriately benefit financially from the current system. In reality, the current ASP-based methodology is designed to cover physicians' drug storage, handling, disposal and administrative expenses, but also maintain access to drugs for smaller practices, and provide protection for providers from the impact of prompt-pay discounts and the two-quarter lag in ASP calculations. Under Part D, the allowed cost reimbursed by plans does not include separate payments for these significant overhead costs, and moving drugs from Part B to Part D would likely make storage, handling, inventory management, disposal and specialized training unaffordable for some providers.

Any proposal to fundamentally change the Part B reimbursement structure must take into account the realities of the current structure for providers. It must sufficiently protect them against drug price increases and the costs of storage, safe handling, and administration. Changes to the current "buy and bill" model would simply lead to further provider consolidation, driving patients to more costly settings of care, and ultimately driving up costs to the Medicare program. The Network is concerned to see another proposal to reform Part B that would harm community-based oncology providers and do little to help cancer patients.

Implementation of CAP-Like Program for Part B Drugs

The Network urges caution in instituting a Competitive Acquisition Program (CAP)- like program for Part B drugs, as such a model could have implications for patient access and provider prescribing flexibility. The shortfalls of the original CAP program, intended to lower prices by increasing negotiation ability, provide an illustrative example. According to the independent CAP evaluation report, only one vendor was ultimately approved, effectively eliminating physician choice within the program. Additionally, the evaluation found that CAP payment amounts for administered drugs in the first 18 months of the program were actually higher than under the ASP-based alternative, resulting in no savings for the Medicare program. For patients, the program led to "very limited to no savings" in terms of cost sharing.[2]

A new program based on the CAP model could share the negative outcomes of the original program as well as present new challenges, depending on its structure. The Network is particularly concerned that a CAP-like model in which a third-party vendor is responsible for elements of the drug supply chain could have significant implications for the storage and safe handling of hazardous drugs. Currently, highly-trained physicians, who have the proven expertise to do so, can safely stock, monitor and administer their patients' drugs. Transferring that power to an outside entity that is not specially trained in providing care for patients could create significant safety risks. This is especially true in cancer care, where complex and volatile drug regimens often require providers to make changes at the point of care, such as dosing adjustments, using their clinical judgment.

[2] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf

We are also concerned that a CAP-like model that uses a formulary and utilization management (UM) could place burdensome restrictions on oncology drugs. These restrictions would not only create access barriers for patients, but would also remove physician prescribing autonomy. Clinical judgment is crucial in making complex treatment decisions for cancer patients. In a recent Community Oncology Alliance (COA) survey of oncologists, hematologists, and rheumatologists, 61 percent of providers said they believe a CAP would diminish their prescribing autonomy and ability to tailor prescriptions to the patient. Additionally, 88 percent said they believe a CAP would take care decisions away from the best person in the best position to make that decision. [3]

While opportunity for improvements exist in "buy and bill", the current structure does appropriately recognize physician management of Part B drugs. These drugs are delivered in the physician office due to the specialized training needed to ensure the integrity of these critical medications including safe handling and temperature controlled storage. Practices in The Network also keep an adequate supply of cancer medication on hand to ensure they are able to treat urgent patient appointments. There is no need to insert additional barriers and decisionmakers when physicians are well-positioned to manage drugs. Because of the potential consequences, we reiterate the need for careful consideration of the impact on both patients and providers of any CAP-like program for Part B drugs

Demonstration to Test Closed Formularies in Medicaid

To avoid potential negative impacts on patient access to care, any Medicaid flexibilities demonstration should be voluntary and narrow in focus, with special protections for cancer patients. Cost considerations should not get in the way of improving patient care, including access to drugs. The vulnerable, low-income Medicaid population, which includes many children with cancer, needs access to clinically appropriate care and all available therapeutic options in a timely manner. Allowing states to develop closed formularies could result in significantly more restrictive drug coverage that is entirely based on cost rather than clinical need. Among oncology drugs, unlike in some other therapeutic areas, there are often no alternative drugs that meet clinical necessity requirements, so it is crucial that patients can receive the particular drug they need. This is why antineoplastics are a protected class under Medicare Part D. Any potential pilot program should include measures to ensure states' formularies allow cancer patients unrestricted access to the drugs their physicians prescribe.

Full Formulary Flexibility for Part D Plans

As with proposals to test closed formularies in Medicaid, The Network is concerned that the administration's proposal to allow Part D plans full formulary flexibility to manage high-cost drugs could reduce access to critical therapies for cancer patients. Specifically, the administration's proposal to make changes to the Part D protected classes could prevent cancer patients from receiving their prescribed therapies. Protected classes exist for a reason: because cancer patients need access to the full range of life-saving therapies that their physicians may prescribe. The administration should ensure this effort to manage drug costs does not prevent vulnerable cancer patients with complex conditions from accessing the drugs they need.

[3] https://www.communityoncology.org/2018/05/16/may-16-coa-physician-survey-medicare-part-b-proposals-will-harm-patients-increase-costs-and-bureaucracy/

Indication-Based Pricing

The administration should work closely with oncology stakeholders to ensure indication-based pricing in Medicare and/or Medicaid would fit the needs of cancer patients. In cancer care, physicians sometimes prescribe drugs for off-label use due to the complex nature of the disease. Advancements in cancer care have led to more personalized, targeted treatment regimens and only a patient's care team can best determine which therapies meet a certain patient's needs. The Network encourages the Administration to carefully consider the unique needs of cancer care when evaluating indication-based pricing proposals.

Positive Proposals to Increase Transparency, Mitigate Consolidation, and Reduce Patient Cost-Sharing

While we urge the administration to proceed with caution on the issues detailed above, The Network commends the administration for the following proposals. We believe these ideas will increase transparency around drug costs and payment, remove incentives for provider consolidation, and reduce patient cost-sharing.

Site Neutrality for Drug Administration

The Network has advocated for payment parity across site of service for several years, and we applaud the administration for continuing to focus on this issue. Treating cancer is costly for both patients and Medicare, and disparities in costs between different sites of care exacerbate those expenses. Total Medicare spending on patients receiving chemotherapy in the community clinic is 14 percent lower than the hospital outpatient department (HOPD), which amounts to $623 million in Medicare savings per year.[4] Additionally, chemotherapy provided in a physician's office costs, on average, 24 percent less than chemotherapy provided in the hospital outpatient setting.[5] In community clinics, patient co-payments are approximately 10 percent lower, amounting to more than $650 in savings for each Medicare beneficiary fighting cancer per year. Additionally, the average out-of-pocket patient cost for commonly used cancer drugs is $134 less per dose if received in an oncologist's office. [6]

These cost differences have a real impact on patients and Medicare. Medicare beneficiaries paid $4 million more in out-of-pocket costs between 2009 and 2012 because of higher patient co-payments associated with higher HOPD rates for chemotherapy services that could have been performed at a community cancer practice for significantly less.[7]

Drugs are not the only care for which patients and the government are overpaying in HOPD settings. All other services are also paid at different rates in different settings of care. According to an Avalere analysis, services provided in the HOPD setting typically have the highest payment rate, compared to ambulatory surgical centers (ASC) and physician offices. Average payments for a 7-day episode following an evaluation and management (E&M) visit in the HOPD are 29 percent higher than in the physician office for a new E&M visit.[8] MedPAC estimates that as a result of payment differentials and growing consolidation, the Medicare program spent $1.8 billion more in 2016 than it would have if

[4] Milliman Client Report: Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy. October 19, 2011. Kate Fitch and Bruce Pyenson. http://publications.milliman.com/publications/health-published/pdfs/site-of-service-cost-differences.pdf
[5] Avalere Client Report: Total Cost of Cancer Care By Site of Service. March 2012. http://www.avalerehealth.net/news/2012-04-03_COA/Cost_of_Care.pdf
[6] Milliman, "Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy," October 2011.
[7] Berkeley Research Group, "Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration," June 2014.
[8] http://go.avalere.com/acton/attachment/12909/f-0298/1/-/-/-/-/20160212%20-%20Payment%20Differentials%20Across%20Settings%20White%20Paper_FINAL.pdf

payment rates for E&M visits were equal to rates for freestanding office visits. The increase in HOPD care also caused patients' cost sharing to be $460 million higher in 2016.[9]

In addition to contributing to high costs for Medicare beneficiaries, reimbursement disparities across settings of care have provided financial incentives for hospitals to acquire physician practices. This consolidation has further led to increased costs and decreased access for patients. MedPAC has specifically hypothesized that payment differentials incentivize hospitals to purchase free standing physician offices and convert them to HOPDs.[10] The prevalence of this practice is clear. From 2011 to 2016, the volume of outpatient prospective payment system (OPPS) clinic visits increased by 43.8 percent and OPPS chemotherapy administration increased by 56.1 percent. Meanwhile, in freestanding physician offices, the volume of office visits grew by only .4 percent, and chemotherapy administration decreased by 13.4 percent.[11]

Medicare should adopt site neutral payments to reduce costs and increase access to care for cancer patients. This could be achieved in a budget neutral way by setting payments for cancer drug administration and other outpatient services at a rate that falls between the current higher rate for HOPDs and lower rate for physician offices. The new consistent rate shared across settings would more appropriately reimburse community oncologists, while removing the unfair payment advantage currently awarded to HOPDs, all while maintaining budget neutrality. We have supported legislation that would equalize payment rates for cancer services during the past two Congresses, including the Medicare Patient Access to Treatment Act of 2015, which would have required changes to payment rates to be budget neutral. When evaluating implementation of site neutral payments in a budget neutral manner, we encourage CMS to ensure patient out-of-pocket costs are not negatively impacted.

The Network also previously commented in support of CMS's implementation of Section 603 of the Bipartisan Budget Act of 2015 (BBA). This policy was an important first step in ensuring the same service is reimbursed at the same rate when clinically appropriate care is delivered across different settings. We will continue to work with Congress and the administration to expand upon the progress made in the BBA.

<u>340B Program Reforms</u>

The Network supports the underlying goal of the 340B drug discount program which is largely aimed at stretching scarce federal resources to benefit indigent patients in critical access areas. **However, we believe the program's recent growth may be contributing to the consolidation of community oncology practices, which limits patient access and has been linked to increased health care costs.** Since 2008,[12] it is estimated that roughly 658 community cancer practices have been acquired by or affiliated with hospitals, with a significant portion of those transactions believed to be leveraged with 340B benefits. This has resulted in a shift in the site of service for chemotherapy administration from the physician-office setting to other, more-costly outpatient settings.

In fact, 10 years ago over 80% of cancer care was delivered in the community-based setting – today that number is closer to 50%.[13] This trend not only creates patient access issues, but often results in higher healthcare and patient

[9] http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0
[10] http://www.medpac.gov/docs/default-source/reports/march-2012-report-to-the-congress-medicare-payment-policy.pdf
[11] http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0
[12] 2018 Community Oncology Alliance, Practice Impact Report. Full Report available at: https://www.communityoncology.org/downloads/pir/COA-Practice-Impact-Report-2018-FINAL.pdf
[13] Milliman Report, April 2016: Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014

out-of-pocket costs. The Network is committed to ensuring all cancer patients receive high quality, clinically appropriate care. We firmly believe in the value of community-based providers providing local solutions to meet the needs of their patients.

For policymakers and regulators to properly assess the scope and value of the 340B program, The Network supports increased transparency through public reporting on meaningful data that provides additional clarity on a covered entity's patient mix, savings associated with enrollment, revenue associated with 340B-eligible outpatient drugs/services and charity care or patient services underwritten by 340B proceeds. We also encourage consideration of separate detailed reporting of these transparency measures for off-campus outpatient facilities to ensure accurate savings and revenue data is understood for child sites that may have a different patient profile than that of the covered entity.

This data is an essential component for informed oversight and will provide an opportunity for eligible entities to demonstrate how they are using funds derived from the program to benefit patient care. To ensure overall program integrity, operability and proper analysis of the data submitted, the Health Resources and Services Administration (HRSA) needs the tools to sufficiently administer and refine the program.

Pharmacy Benefit Manager (PBM) Practices and System Incentives

The Network appreciates the administration's recognition of the perverse incentives at play for PBMs that prevent transparency in our current system. Specifically, PBMs' practice of steering patients to PBM-owned mail order or specialty pharmacies, the use of retroactive pharmacy price concessions, and pharmacy gag clauses are important issues that limit patients' access to convenient, affordable care. We believe the administration should pursue policies specifically directed to curb these harmful practices when considering changes to PBM practices and incentives.

We have increasingly seen PBMs directing cancer patients to use a PBM-owned mail order or specialty pharmacy to obtain their oral chemotherapy, which can result in higher costs. In some cases, patients must bring their medications to their physician's office themselves, creating storage and handling concerns. In the oncology care space, many community-based cancer clinics have established medically integrated pharmacy platforms or practice-based pharmacies so patients can access their oral chemotherapy prescriptions or other medications at the point-of-care. Practices with medically integrated pharmacy services have been shown to significantly improve patient adherence,[14] ensure the timely receipt of prescribed drugs,[15] and improve outcomes[16] at a lower cost.[17] Forcing IOD practices and practice-based pharmacies out-of-network and requiring patients to instead receive oral oncolytics through a PBM-owned pharmacy can result in drug delivery complications and processing errors. These errors could delay critical medications for very sick patients. The Network has previously supported legislation (H.R. 1316) to prohibit PBMs from requiring patients to use PBM-owned pharmacies and empower patients to fill their prescription at the site of their

[14] Pauline W. Chen, When Patients Don't Fill Their Prescriptions, N.Y. Times (May 20, 2010), available at: http://www.nytimes.com/2010/05/20/health/20chen.html?_r=0.
[15] Lee Schwartzberg et al., Abandoning Oral Oncolytic Prescriptions at the Pharmacy: Patient and Health Plan Factors Influencing Adherence (2010), available at: http://www.communityoncology.org/pdfs/asco-poster-handout.pdf.
[16] Michael A. Fischer et al., Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions, 25 J. Gen. Intern. Med. 284 (Apr. 2010), available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842539/pdf/11606_2010_Article_1253.pdf.
[17] See William Shell, The History of Physician Dispensing, Complete Claims Processing Inc., available at: http://www.ccpicentral.com/history-of-physician-dispensing.php (last visited Jan. 10, 2018).

choosing. We similarly encourage the administration to use its authority to prevent these harmful PBM practices to improve patient choice and care.

Additionally, the current pharmacy price concession structure fails to allow for meaningful price comparisons, does not encourage price transparency, and is not optimal for producing the lowest overall prescription drug costs for beneficiaries. The Network is particularly concerned that retroactive pharmacy price concessions act as a disincentive to practices operating IOD platforms and practice-based pharmacies. This is because pharmacy price concessions are calculated and applied retrospectively, forcing practices to guess the amount of PBM "clawbacks" after the point of sale. It is difficult for practices to positively impact the level of direct and indirect remuneration (DIR) fees because they are often based on targets beyond practices' control, such as CMS star ratings. When DIR fees are percentage-based, they can have a particularly unfair negative effect on practices that dispense high-priced specialty medications through IOD. We previously commended CMS's proposal to include pharmacy price concessions at the point of sale in the CY 2019 proposed Part D rule. We encourage the administration to implement that change and continue to create transparency in DIR fees. Ultimately, DIR fees should benefit patients and not unfairly harm practices.

We applaud the administration's efforts to address Part D plan actions that prevent pharmacists from discussing lower out-of-pocket cost options with beneficiaries. Similarly, we encourage the administration to extend this transparency policy to PBMs as PBMs have continued to use pharmacy gag clauses which are stronghanded tactics to limit consumer information about drug pricing in the pharmacy setting. This can result in higher out-of-pocket costs. Patients should be able to access their drugs with the lowest possible out-of-pocket costs possible and must be fully informed to do so. If patients can save money on their drugs by paying cash, pharmacies should be able to tell them.

Increasing Price Transparency

The Network supports efforts to provide beneficiaries with additional cost information to facilitate decision-making. Price transparency across the healthcare system is crucial to lowering beneficiary costs. This includes ensuring beneficiaries have the tools and resources available to understand their own healthcare costs. As providers of high-quality, lower-cost care, community oncologists support educating beneficiaries, so they may make informed decisions regarding their care. Specifically, we support ensuring that Medicare patients can access information on out-of-pocket costs when deciding on their site of care, so that they may make decisions based on the true cost to the patient.

Additionally, the 21st Century Cures Act directed CMS to develop a public database in which Medicare beneficiaries may compare the costs of procedures between HOPD and ASC settings. The Network believes this tool should be expanded to include the physician office setting, so that beneficiaries may view a complete apples-to-apples comparison of costs across all potential settings of care, including the lower cost physician office.

Value-Based Payment Models

The Network is highly supportive of value-based care models that improve quality and lower costs of care for beneficiaries and the health system. We appreciate that opportunities exist within cancer care to demonstrate value, improve quality, strengthen patient outcomes, and hold down costs. In fact, The Network has been at the forefront of value-based care and payment in oncology through its development of the Pathways program and participation in the Oncology Care Model (OCM), two value-based care models working to improve patient outcomes and cost savings in cancer care.

Nearly a decade ago, physicians in The Network recognized an opportunity to strengthen relationships with patients and payers by selecting regimens that demonstrate value over volume and reduce non evidence-based variability in treatment. As a result, we developed the Level I Pathways, evidence-based guidelines that re-direct the wide range of oncology treatments into more precise, clinically proven treatment options. The Pathways are physician-driven and designed to reduce variability, hospitalizations, and excessive care at the end of the life. The guidelines are developed and updated by a multidisciplinary task force, along with a network of more than 1,400 community oncologists.

According to a study in the Journal of Oncology Practice on patients treated both with and without the Pathways program, adherence to Pathways lowered overall costs of care with equal or better outcomes. The results included a 22% lower frequency of chemotherapy infusion visits, a 23% lower frequency of non-chemotherapy agents, and a 35% reduction in outpatient costs.[18] A follow-up study found the median overall survival for Pathway patients with colon cancer was 26.9 months, vs. 20.1 months for non-Pathway patients. The 1-year estimated survival for Pathway patients was 80%, compared to 74% for non-Pathway patients.[19]

Our dedication to providing high-quality, integrated cancer care is also demonstrated by the 16 oncology practices within The Network, encompassing roughly 900 providers, that have been selected to participate in CMS's OCM. These practices have accepted the challenge of participating in the pilot with the shared goal of improved patient outcomes and cost savings for the Medicare program. We embrace innovation in both treatment options and care delivery, and we are committed to working with the administration toward policies that enable physicians to practice medicine so that patient outcomes are improved, rather than compromised. It is expensive for cost-conscious oncology practices to build the infrastructure to support value based care. We know cancer care costs and drug prices continue to rise. We are making the effort to manage costs and look to reimbursement strategies that recognize this transition to value-based care.

As the administration looks to develop or expand upon value-based care initiatives to improve quality and patient outcomes while holding down costs, it should do so in close collaboration with physicians, patients, and other stakeholders.

Reducing Patient Out-of-Pocket Costs

The Network is supportive of the administration's efforts to reduce out-of-pocket costs for patients. Given the potentially high costs of cancer care, it is important that charitable assistance and other options are available to provide patients and their families with much needed financial support. Medicare beneficiaries may face particularly high out-of-pocket expenses for prescription drugs, including cancer drugs.

There are many patient advocacy organizations and pharmaceutical manufacturers that provide critical support to cancer patients through charitable foundations. For example, a recent analysis found that one foundation, Patient Services, Inc. (PSI), provided $70.9 million in cost-sharing assistance in 2017 to 13,500 Medicare Part D patients, including 6,400 cancer patients.[20]

[18] https://www.ncbi.nlm.nih.gov/pubmed/20539725
[19] https://www.ncbi.nlm.nih.gov/pubmed/21886520
[20] http://go.avalere.com/acton/attachment/12909/f-0548/1/-/-/-/-/Avalere%20Patient%20OOP%20Assistance%20Part%20D%20Analysis.pdf

Financial assistance can help reduce patients' out-of-pocket costs and improve access to necessary treatments. Financial assistance in Part D also reduces Medicare spending on Parts A and B. According to one analysis, $1 million from PSI reduces spending on Parts A and B by $1.83M, translating to nearly $130 million in total Part A and B savings in 2017.[21] Beyond prescription drug support, many foundations also offer holistic support to help ease the burden for families, such as providing funds for patients' living expenses.

Currently, foundations that choose to provide financial support to help Medicare patients with out-of-pocket costs associated with cancer treatment face significant hurdles. We urge the administration to consider the merits of allowing patient assistance in federal programs in order to improve affordability and outcomes. Such change would allow patients covered under federal programs to benefit from cost-sharing assistance in the same way as those insured by commercial plans.

As the administration considers the role of cost-sharing support in public programs, The Network also urges the administration to examine emerging payer practices in the commercial market that are increasing costs to patients. In particular, copay accumulator programs are designed not to count any copay assistance toward enrollees' deductibles and out-of-pocket maximums. These programs effectively shift a greater share of drug costs to patients. In addition, the lack of transparency into these programs creates additional confusion for patients.

As described above, The Network is supportive of and committed to value-based care models that improve quality and lower costs of care for beneficiaries and the health system. Importantly, these arrangements have the potential to reduce out-of-pocket costs for patients while improving health outcomes. In considering the design elements of any value-based contract, we believe a reduction in patient out-of-pocket costs is an important feature.

Conclusion

On behalf of The US Oncology Network, thank you for the opportunity to provide our comments on the Request for Information on the US Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. We welcome the opportunity to discuss the issues outlined above and other critical issues impacting community cancer care with you and your staff. Should you have any questions, please contact Ben Jones, Vice President of Government Relations and Public Policy, at Ben.Jones@usoncology.com.

Michael Seiden, MD
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The US Oncology Network

[21] http://go.avalere.com/acton/attachment/12909/f-0548/1/-/-/-/-/Avalere%20Patient%20OOP%20Assistance%20Part%20D%20Analysis.pdf