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July 16, 2018

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

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

RE: Request for Information on U.S. Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (CMS-2018-0075-0001)

On behalf of the Board of Directors of the Community Oncology Alliance (COA), I am submitting this comment letter in response to the U.S. Department of Health and Human Services (HHS) Request for Information on the President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (HHS-OS-2018-0010) (RFI).

COA is dedicated to advocating for community oncology practices and, most importantly, the patients they serve. COA is the only non-profit organization focused solely on independent community oncology, the setting where the majority of Americans with cancer are treated. The mission of COA is to ensure that cancer patients receive the highest quality, most affordable and accessible cancer care in the communities where they live and work. For over 15 years, COA has built a national grassroots network of community oncology practices to advocate for public policies that benefit cancer patients. Individuals from all perspectives of the cancer care delivery team – oncologists, administrators, pharmacists, mid-level providers, oncology nurses, patients, caregivers, and survivors – volunteer their time on a regular basis to lead COA and serve on its committees.

As the frontline providers of care for the majority of Americans battling cancer, community oncologists are highly aware that the trend of continuously increasing drug prices and cancer care costs are unsustainable and unacceptable. We commend the administration for prioritizing efforts to address this important and complex issue affecting both patients and their providers. **Ensuring access to affordable life-saving cancer treatments is a top concern for oncologists, oncology nurses, practice administrators, pharmacists, and other cancer care professionals.** COA believes that every stakeholder – *starting with the pharmaceutical industry* – in our incredibly complex health care system must come together and selflessly collaborate to reduce medical costs. We strongly believe that with joint efforts from stakeholders from every corner of the health care system, we can – *and must* – find a solution to high drug prices.

We want to caution, however, that it is important for this administration to focus on the true drivers of health care spending and misaligned incentives, and to avoid new policies that would result in unintended consequences for our patients, their families, and their care teams. History has documented that even well-intended policymaking can backfire, harming patients, increasing costs, and limiting access to care. This has been particularly true in cancer care – especially with Medicare Part B (Part B) – where Americans today are facing the financial impact of previous misguided policymaking.

In this letter response to the RFI, COA will highlight and underscore that any shifts of cancer drugs from Part B to Medicare Part D (Part D), increases in the roles, leverage, and power of third party middlemen, such as Pharmacy Benefit Managers (PBMs), or further increasing formulary flexibility for Part D plans will threaten to decrease patient access to treatment, increase their costs, and compromise the viability of community oncology without generating the desired Medicare savings. *In fact, history teaches that Medicare spending increase.* Instead, we call for efforts to curb abuses by PBMs and to fix the broken 340B Drug Discount Program such that patients in need benefit from 340B savings, not hospitals' bottom lines.

COA is providing specific input on the following topics relating to the RFI and HHS' stated reform goals:

- **Increased Competition**
 - Accelerating the FDA regulatory process and facilitating generic and biosimilar competition
- **Better Drug Negotiation**
 - Leveraging the existing authority under Part B's Competitive Acquisition Program (CAP) to reinstate the program
 - Transitioning some products from the Medicare Part B program into Part D
 - Introducing site-neutral payments for oncology services
 - Improving transparency, accountability, and oversight of the 340B program
 - Priority areas for Part B reform
- **Lower Drug Prices**
 - Increasing Medicare Part D plan sponsor flexibility
 - Role of rebates and PBMs
 - Facilitating value-based purchasing (VBP) arrangements, including indication-based pricing

We have outlined our comments and recommendations based on HHS's questions and proposals below, including proposals we are concerned will negatively impact patient access and oncologist-patient treatment choice, as well as the policies we believe will help improve the affordability, transparency, and access to innovative cancer medications.

We want to underscore COA's commitment to oncology payment reform, including cancer drug pricing, utilization, and spending. As such, we summarize recommendations in this area that are not specifically contained in questions posed in the RFI.

INCREASED COMPETITION

Accelerating the FDA regulatory process and facilitating generic and biosimilar competition

COA supports thoughtful reforms to accelerate Food and Drug Administration (FDA) approval of generic drugs and biosimilars to promote competition and expand access to more affordable medicines. Numerous stakeholders, including the FDA, recognize that increased generic competition is associated with lower drug prices.¹

Regulatory reforms are needed to ensure robust competition, particularly with regard to biosimilars. We note that the policy change to assign each biosimilar for a given biologic its own unique billing and payment code under Medicare Part B was an important first step to incentivize further biosimilar development and to ensure a healthy, robust, and competitive biosimilar market, especially given that the U.S. lags other parts of the world in biosimilar availability.

The cost of development and the lack of competition in the biologics market has led to high prices that can create access barriers for patients. Studies have shown that while approximately one to two percent of the population use biologic drugs, they account for nearly 40% of America's prescription drug spending.²

¹ <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm>

² Rand Corporation. Biosimilar Cost Savings in the United States. 2017.

https://www.rand.org/content/dam/rand/pubs/perspectives/PE200/PE264/RAND_PE264.pdf

A vibrant biosimilars market has the potential to reduce costs in our health care system and improve access and affordability for millions of patients, especially relating to biologic cancer drugs. However, lessons from the generic market, which is marked by consolidation, decreased redundancy of manufacturers, and ongoing generic drug shortages, must be heeded in facilitating the development of a healthy biosimilar market.

Regarding shortages of generic drugs, although manufacturing deficits are frequently cited as the problem, those are just a symptom of underlying fundamental financial and economic causes. If generic drug manufacturers cannot make an adequate profit they will either choose not to produce certain drugs or spend as little as possible on manufacturing quality control. It is not a coincidence that as mandatory statutory discounts and rebates – primarily 340B discounts and Medicaid rebates – have increased in both scope and magnitude that shortages of generic drugs have become an ongoing reality that has not been solved. These shortages have plagued cancer care and hospital emergency departments. Mandatory discounts and rebates reducing the price of generic drugs to a penny are simply not realistic.

An outgrowth of this situation with generic drugs is the increasing tendency of manufacturers when they are the sole producers to take exorbitant price increases. This situation has also opened the door to unscrupulous financial operators to buy single-source generics to exorbitantly mark up the prices of these drugs.

- Recommendation: Additional policies are needed to further encourage the development of new biosimilars and foster much needed competition in this market. COA is ready to work with the FDA and HHS/CMS in fostering the adoption of biosimilars, including examining ways to tweak the Part B reimbursement system.
- Recommendation: Drugs in short supply need to be exempted from mandatory statutory discounts and rebates. This should also pertain to single source generics to incentivize additional manufacturers into the market. We realize that this will likely require legislation, but this is essential to reviving a broken generic market.

BETTER DRUG NEGOTIATION

Growth in the Medicare Part B program has been under much scrutiny recently and oncology care is often cited as the therapeutic area where most spending is concentrated. The reality is that in the past couple of decades, oncology innovation has transformed cancer treatment with many new molecules and targeted therapies achieving major gains in survival and quality of life. Furthermore, the aging of the U.S. population, the earlier detection of cancer, and the increase in cancer survival have put pressure on Medicare spending, but any efforts to address cost growth by limiting access to all this important innovation would be detrimental.

COA is very concerned about the negative patient impact that would result from proposed changes to the Medicare program that would introduce third-party, PBM-type middlemen entities to the Part B program or shifting some prescription drugs currently paid for under Part B to a Medicare Part D program that is currently dominated by PBMs. These changes do not consider the negative experience and increased costs that patients currently face in dealing with PBM middlemen in the Medicare Part D system.

Leveraging the existing authority under Part B's Competitive Acquisition Program (CAP) to reinstate the program

As we have expressed in the past, reintroducing a CAP-like model to add middlemen into Part B drug distribution and administration will lead to the same patient challenges experienced under Part D, where the PBMs are unduly complicating drug procurement, delaying and denying patients treatment, and driving up costs. The CAP program, as an alternative to the average sales price (ASP) methodology for paying for Part B drugs, has been suspended for almost a decade because experience with it showed negative impacts on access and supply chain dynamics, while the projected cost savings never materialized. For the duration of the first CAP vendor contract, it is estimated that CAP was not

budget neutral due to overpayments by Medicare, relative to ASP-based pricing.³ This means that the program did not effectively lower costs for Medicare or patients, while adding complexities to drug negotiations and procurement.

Looking ahead, the administration recognizes that it has the statutory vehicle to bring back the CAP program, but COA is concerned that trying to revive a failed experiment may once again jeopardize patient access without adding any benefit to the existing competition and negotiation for Part B drugs.

Allowing middlemen to negotiate drug prices is particularly dangerous in cancer care because there are few therapeutic and generic-to-brand substitutes, so patients need uninhibited access to the therapies their oncologists prescribe. Furthermore, cancer care has become personalized in that not all therapies produce the identical result patient to patient. Having therapy options is imperative to the successful treatment for each Medicare beneficiary.

We also caution against the Medicare Payment Advisory Commission's (MedPAC's) alternative proposal of a Drug Value Program (DVP) which envisions introducing formularies and utilization management in Part B.⁴ This would be a strong departure from the physician-directed, evidence-based prescribing that is the norm today in cancer treatment. Importantly, people with cancer also heavily rely on access to medically appropriate off-label use of oncology drugs and biologics, which could also be at risk under the DVP model. A CAP-like program will ultimately reduce prescriber autonomy and create a system where patients' care is determined by middlemen, rather than their doctors. To some degree, formulary management is occurring now in the private sector, and COA has accumulated a library of horror stories resulting from those therapy restrictions.⁵

A recent COA survey found that providers are very concerned about how resurrecting a CAP-like program would affect their patients. In total, 88% of providers believe a CAP or DVP program would take care decisions away from the person in the best position to make such decisions. More than 87% of respondents expect that it would limit their ability to provide the best care to patients and about 75% think it would increase the administrative burden for their practices.⁶ This last point on increased administrative burdens to practices cannot be underscored enough. Whether CAP will be run as a special, separate inventory system or a patient-by-patient "white bag" system, the logistics for a community oncology practice will be daunting. Additional staff would be required to administer this type of program with no means of covering the costs for staff and associated logistical support.

Last, but not least, we want to remind the administration to consider all these proposals within the broader context of a shift to value-based care and increased financial risk for providers in Medicare and beyond, which would ultimately be passed on to patients. Both COA and CMS have invested heavily in the Oncology Care Model (OCM), an alternative payment model we believe can be a success for both patients and providers. HHS must consider the impact that its proposals to change the Part B program would have on patients benefiting from this and other ongoing value-based models. It would be an unfortunate loss of years of effort and resources if implementing a CAP-like program or shifting drugs from B to D threatens the quality and cost performance under the OCM.

Transitioning some products from the Medicare Part B program into Part D

COA strongly opposes any efforts by the administration to bypass Congress in changing Part B drug reimbursement by shifting complex biologics that are statutorily covered under Part B into Medicare Part D. This would mean increasing the power and prevalence of the PBM corporate middlemen that dominate the Part D system at a time when both policymakers and the public have a heightened awareness of the business model with distorted incentives that have allowed PBMs to grow their influence and harm patients, all without reducing costs. Moving cancer drugs from Part B

³ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf

⁴ http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0

⁵ <http://bit.ly/pbmstoriesv1> , <http://bit.ly/pbmstoriesv2> , <http://bit.ly/pbmhorrorstoriesv3>

⁶ <https://www.communityoncology.org/2018/05/16/may-16-coa-physician-survey-medicare-part-b-proposals-will-harm-patients-increase-costs-and-bureaucracy/>

to Part D will not only bring the multitude of issues currently facing patients and community oncologists in the Part D program to the Part B program, but it will also create new operational and reimbursement challenges.

Higher Out-of-Pocket Costs: Comparing out-of-pocket (OOP) costs between Medicare Part B and D is complex, because of the different structure of the benefits, so the impact of a proposed shift in drug coverage will vary based on patient income and their total drug usage. However, we are learning that for most beneficiaries, this transition will have a negative effect on affordability. A recent analysis by Avalere shows that in 2016 seniors' OOP costs were 33% higher for Part D-covered new cancer therapies (\$3,200) than for those covered in Part B (\$2,400).⁷ Among Part D beneficiaries who do not qualify for low-income cost-sharing subsidies (about two thirds of all enrollees), average OOP costs were even higher – \$4,400, on average. Additionally, Avalere notes that shifting Part B drugs into Part D “could put upward pressure on Part D premiums, which may not be fully offset by a decrease in Part B premiums, because the Part B program pays for both drugs and physician services.”⁸

Even patient costs for generic drugs under Part D have been on the rise. In many cases, this is because Part D plans have increasingly placed generics on higher cost-sharing tiers despite stable drug prices. The number of generic drugs placed on the lowest cost-sharing tier decreased by 53% from 2011 to 2015,⁹ thus nearly doubling some patients' cost sharing over a 5-year period.¹⁰ Last, but not least, in the RFI the administration recognizes that an estimated 27% of Part B beneficiaries are not enrolled in Part D, so shifting Part B drugs into Part D will likely lead to serious affordability and access challenges for about a quarter of seniors under Medicare.

Tremendous Billing, Reimbursement, and Operational Issues: It is important to clarify that whereas Part D involves oral or other self-administered medications, Part B cancer therapies are injectable drugs, such as chemotherapy. These must often be transported under temperature-controlled conditions, carefully stored at the site-of-care, and administered under close physician supervision due to potential toxicities and serious side effects.¹¹ Part D plans typically contract with pharmacies, not physicians, so a shifting of Part B drugs into Part D will result in a list of billing and reimbursement challenges for providers if cancer drugs are consolidated under the outpatient drug benefit. If they are not included in the Part D plans' networks, oncologists may be unable to file claims directly, verify beneficiary coverage, and estimate cost-sharing liability. Furthermore, the “plus 6%” add-on to ASP under Part B is designed to compensate physicians for the storage, handling, and other administrative costs associated with procuring, inventorying, and preparing injectable oncolytics. There is no such mechanism under Part D to compensate for those very real costs, thus potentially impacting a provider's ability to store and handle drugs and instead relying on white bagging, specialty pharmacies, or expensive hospital care. This will certainly place hurdles in front of cancer patients getting treated on a timely basis and could even limit patients' access to treatment.

For the potential impacts on patient access to therapies outlined above, COA is very concerned about the proposal to shift of Part B drugs into Part D. We surveyed 100 oncologists/hematologists and 50 rheumatologists and found that 85% of providers believe moving Part B drugs to Part D will create affordability issues for patients, 89% of responders believe it could delay treatment access, 92% believe it would reduce treatment choices, and 93% of providers believe it will increase their administrative burden.¹²

⁷ <http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d>

⁸ Ibid.

⁹ <http://avalere.com/expertise/life-sciences/insights/seniors-pay-more-for-generics-in-medicare-prescription-drug-plans-despite-s>

¹⁰ <http://avalere.com/expertise/life-sciences/insights/seniors-pay-more-for-generics-in-medicare-prescription-drug-plans-despite-s>

¹¹ https://www.communityoncology.org/wp-content/uploads/2018/05/COA_HHS-Sequester_Letter_5-30-18_FINAL.pdf

¹² <https://www.communityoncology.org/portfolio-items/coa-physician-survey-medicare-part-b-proposals-will-harm-patients-increase-costs-and-bureaucracy/>

Introducing site-neutral payments for oncology services

COA strongly believes that different reimbursement structures based on site-of-care have in part incentivized provider consolidation into the much more expensive hospital setting, increasing costs for seniors and Medicare. Higher Medicare and private payer reimbursement for outpatient oncology services provide significant financial incentives for hospitals to purchase physician-owned community oncology practices when coupled with the very profitable 340B program. When a hospital acquires a community oncology practice, in many cases the practice continues to operate exactly as it did before the acquisition; the only exception being that the hospital now controls the billing. A cancer patient can receive the same chemotherapy at the same location, prescribed by the same oncologist, and administered by the same oncology nurse, but the bill (now sent by the hospital) is significantly higher. This includes both higher billings for services, such as chemotherapy administration and add-on hospital facility fees.

Acquiring existing community oncology practices is the fastest, most efficient way for hospitals to expand their cancer treatment footprint and increase profits. This can be particularly devastating in rural areas. According to the American Society of Clinical Oncology's (ASCO) recent workforce analysis, whereas 20% of the US population resides in rural areas, only three percent of medical oncologists' practice in rural areas. For patients in areas with no local oncologist, it was estimated that patients travel on average 58 minutes, with many traveling an hour and a half or more each way to receive chemotherapy, adding cost and burden to them and their caretakers.¹³ Physician retirements and financial pressures on small community oncology practices, coupled with the increasing number of aging baby boomers seeking cancer treatment, will undoubtedly exacerbate access issues in rural areas in the coming years.

Meanwhile, in cases where community oncology practices choose to remain independent and merge with hospitals, they face other challenges, such as changes in referral patterns by hospital employed physicians. COA wants to call HHS' attention to these practices to ensure that there are no regulatory barriers preventing community oncologists from providing effective, efficient care to cancer patients.

- Recommendation: We applaud the administration for recognizing that site payment parity, whereby the same services are paid at identical rates, regardless of the site-of-care – hospital or independent oncology practice – should be a priority in the HHS roadmap to address drug pricing. COA strongly supports additional legislative and regulatory efforts to create site-neutral payments for all hospitals, general and cancer-specific, for vital oncology (and associated hematology) services, with no exceptions.¹⁴ COA specifically recommends no special carve-outs for dedicated large cancer hospitals that spend millions of dollars advertising their services, while taking advantage of Medicare billing exemptions that result in significantly increased costs for beneficiaries, Medicare, and taxpayers.

Improving transparency, accountability, and oversight of the 340B program

The 340B program provides a valuable safety net for helping to ensure that both uninsured and underinsured patients receive medical treatment. COA strongly supports the 340B program and believes it should be preserved to ensure that vulnerable patients have access to the care they need. However, the 340B program today is out of control and being abused, particularly by a growing number of bad actors in the hospital sector.

This tremendous growth of the 340B program is of particular concern to COA, community oncology, and the cancer patients we treat. The opportunity for hospitals to make substantial profits from cancer drugs purchased through the 340B program has created substantial financial incentives for hospitals to expand oncology services, either through internal expansion or acquisition of independent, community oncology practices. The resulting shift of cancer care to

¹³ <https://www.asco.org/research-progress/reports-studies/state-cancer-care>

¹⁴ http://www.communityoncology.org/UserFiles/COA_EnCLetter_SiteNeutrality_2-18-16.pdf

the much more expensive hospital setting is costing cancer patients, Medicare, and all taxpayers more -- \$2 billion increased cost to Medicare in just one year (2014).¹⁵

There is also mounting evidence that the exploding volume of 340B discounts is fueling drug prices. A study by the Berkeley Research Group found that *“Growth in 340B purchases of oncology drugs and the expansion of Medicaid tripled the volume of statutory discounts and rebates on drug sales between 2010 and 2015, putting upward pricing pressure on drugs accounting for these discounts and rebates... Additional upward price pressure for launch drugs exists because the 340B price can only increase at the rate of inflation. As a result, pharmaceutical manufacturers must account for the likely continued expansion of 340B utilization in the future to properly price a drug. Given recent growth trends in the 340B program, manufacturers are likely anticipating greater 340B utilization in the future and factoring it into launch prices.”*¹⁶

We are certain that CMS is familiar with all the data and analyses on various aspects of the 340B program but would like to highlight a few important findings related to how the 340B program has severely veered from its original intent and how patient care is now being adversely impacted.

Originally started by Congress in 1992 to support a handful of safety net hospitals, the 340B program has grown substantially from a few hundred participating entities in 2005 to more than 12,000 qualifying entities and more than 38,000 total sites in 2017. The 340B program allows qualifying entities to realize increased revenue by accessing 30-50% discounts on outpatient drugs. In 2017, 340B program drug purchases amounted to \$19.3 billion, which is at least five percent of the U.S drug market.¹⁷ However, looking at Part B oncology drugs, 340B hospitals now account for 67% of all Part B drug reimbursement.¹⁸

The scale and impact of the 340B program has also grown substantially through the use of 340B hospital-contract pharmacy relationships. Starting in 2010, 340B covered entities were allowed to contract with an unlimited number of unaffiliated pharmacy partners to fill prescriptions. Since that time, the number of contract pharmacies has increased significantly, from about 1,300 at the beginning of 2010 to over 21,000 in 2018.¹⁹ Now, close to one out of three pharmacies are 340B contract pharmacies, with five chains accounting for two-thirds of that contract pharmacy business.

Federally qualified community health centers, hemophilia treatment centers, and other community safety net providers are generally required to demonstrate that services are provided to needy or certain vulnerable populations and that there is a reinvestment in those services. These providers are held to high standards of transparency and accountability. The same is not always true in the case with non-profit hospitals, where 340B eligibility is determined in part on their disproportionate share of Medicare and Medicaid inpatient days. That means that while the 340B program only applies to certain outpatient drugs, eligibility is determined by using an inpatient metric. This methodology does not sufficiently guarantee that individuals most in need are provided with the affordable cancer medications they need. In fact, a 2018 *New England Journal of Medicine* study found that 340B program eligibility was associated with 90% higher parenteral hospital drug claims for Medicare hematology-oncology patients, but lower proportions of low-income hematology-oncology patients and no significant differences in the provision of safety-net or inpatient care for local low-income populations.²⁰ These findings suggest 340B hospitals have higher utilization without corresponding increases in care for their target population of low-income patients.

Additionally, a June report from the Government Accountability Office (GAO) found that some contracting with 340B pharmacies incentivize the utilization of higher-cost drugs over comparable less expensive alternatives.²¹ This is due to

¹⁵ <https://www.communityoncology.org/pdfs/Trends-in-Cancer-Costs-White-Paper-FINAL-20160403.pdf>

¹⁶ <https://www.thinkbrg.com/newsroom-publications-vandervelde-blalock-340b-size.html>

¹⁷ <https://www.drugchannels.net/2018/07/our-exclusive-analysis-nearly-one-in.html#more>

¹⁸ <https://www.thinkbrg.com/newsroom-publications-vandervelde-blalock-340b-size.html>

¹⁹ <https://www.drugchannels.net/2018/07/our-exclusive-analysis-nearly-one-in.html#more>

²⁰ <https://www.nejm.org/doi/full/10.1056/NEJMs1706475>

²¹ <https://www.gao.gov/assets/700/692697.pdf>

the current reimbursement dynamics of the 340B program, where drugs can be obtained with substantial discounts from drug manufacturers, but pharmacies can bill insured patients for the full price of the drug without considering the discount. Consequently, there are clear incentives for increased revenue when administering a more expensive branded drug versus a generic, leading to potential access challenges for patients and increased costs for the broader health care system. In fact, this very issue was something identified by the GAO in a 2015 report which found that patients at 340B hospitals were “either prescribed more drugs or more expensive drugs” than patients at non-340B hospitals.²²

Moreover, as noted earlier, the 340B program and the associated deep drug discounts raise costs for patients by creating perverse incentives used by hospitals to acquire physician-owned community cancer clinics. An analysis of consolidation data for 2013 and 2014 shows that every three out of four acquisitions were by 340B hospitals. Since the 340B statute does not require covered entities to track or report program savings or how they are used, they can direct savings to fund new buildings and facility upgrades or executive compensation, not for supporting patients in need in the community.

COA’s unwavering position is that the 340B program is critically important and must be preserved. However, it is being abused by an increasing number of hospitals and requires transparency and accountability, and a clear definition of an eligible patient, to ensure that program resources are more closely aligned with ensuring that indigent uninsured and underinsured patient receive the care that they need.

- Recommendations: COA calls on HHS — specifically, the Office of Pharmacy Affairs within the Health Resources and Services Administration (HRSA) of HHS — and Congress, given the limits of HRSA regulatory authority, to strengthen the 340B program by issuing regulations and/or passing legislation that accomplish the following:
 1. Revise the criteria and metrics for determining 340B eligibility for nonprofit hospitals. We should better align 340B discounts with the delivery of indigent care and to ensure that 340B hospitals are true safety net facilities treating a documented disproportionate share of uninsured and underinsured patients. Eligibility based on the current disproportionate share hospital (DSH) metric is inappropriate because the DSH metric is based largely on inpatient care whereas the 340B program covers outpatient drugs. The 340B eligibility formula must be based on a measure of uninsured and underinsured outpatient care.
 2. Increase transparency and accountability among 340B hospitals. 340B eligibility for hospitals should be similar in transparency and accountability as eligibility requirements for community health centers and similar qualifying 340B entities.
 3. 340B hospitals should be required to provide financial reports on 340B savings and the percentage of those savings used to provide care to uninsured and underinsured patients.
 4. Ensure that patient care is not compromised by 340B entities due to financial incentives from discounts on high cost cancer drugs.
 5. Clarify specific 340B program definitions, including eligible patient, covered entity, and outpatient department.
 6. Ensure that HRSA has sufficient resources and funding to properly regulate and audit the 340B program, commensurate with the program’s growth.
 7. Ensure that 340B program discounts are actually being used to help patients in need. Hospitals that are indeed using 340B discounts to help patients in need from falling through the “treatment cracks” should not be concerned about greater program accountability and transparency, as are required of the federal grantees participating in the program.
 8. 340B should be redesigned such that the 340B discount follows the patient, regardless of the site of care, and the patient should benefit from the discount.

²² <https://www.gao.gov/products/GAO-15-442>

Priority areas for Part B reform

The administration's proposals to curb growth in spending on Part B drugs appears to be rooted in the faulty notion that providers benefit financially from the current reimbursement methodology and are incentivized to prescribe expensive drugs. Not only is this demonstrably wrong and contrary to published data, it is deeply insulting to the millions of dedicated community oncology professionals across the country.

The "plus 6%" add-on to ASP is designed to cover providers' acquisition, storage, handling, administration, and disposal costs associated with their patients' complex and often toxic Part B drugs. It also serves as a buffer when practices purchase drugs at prices above the "average" in ASP. Given the tremendous and complex variations in drug prices that are impacted by practice size, purchasing volume, negotiating power, and other variables, this is a common occurrence.

It must also be noted that, in reality, due to CMS' wrongful application of the sequester cut to Part B drug reimbursement, providers are actually only reimbursed at ASP plus 4.3%. When also accounting for the impact of prompt pay discounts and the lag in ASP calculations, many oncologists may receive net Medicare reimbursement that is below drug acquisition costs. A recent Avalere analysis found that 21% of all Part B drugs analyzed had a negative estimated difference between drug acquisition cost and the Medicare allowable payment amount. The same analysis found that among the top 10 highest cost cancer drugs (accounting for 72% of all cancer drugs and 23% of all Part B drug spending in 2016), the average estimated difference between drug acquisition cost and Medicare allowable payment amount is 2.4% or \$2.50.

Due to the unconstitutional and illegal application of the sequester cut to Part B reimbursement, community oncologists are already struggling to survive. The application of the sequester cut to cancer drug payments has set up the nation's cancer care system for the closure and consolidation of independent community oncology practices, where the majority of Americans with cancer are treated. This has created access problems for patients as cancer care moves into the much more expensive hospital system, driving up costs for seniors with limited mobility and fixed incomes, as well as all taxpayers who fund Medicare.

As the 2018 Community Oncology Practice Impact Report notes, since the sequester started in 2013, approximately 135 independent community cancer clinics – many comprised of multiple locations – have been forced to close their doors, and approximately 190 clinics have been acquired by hospitals.²³ The actuarial firm Milliman found that the consolidation of community cancer practices into hospitals cost Medicare and taxpayers an extra \$2 billion in 2014 alone. In addition, Medicare beneficiaries responsible for the 20% coinsurance saw their bills rise by \$500 million in that same year.²⁴

- Recommendation: We call for the administration to end the sequester cut on Part B drug reimbursement, which would strengthen the viability of community providers and therefore also save money for Medicare and beneficiaries.

Despite financial uncertainties around reimbursement for cancer therapies, community oncologists believe the current Part B system is in the best interest of cancer patients. It offers the flexibility to use and administer the most clinically appropriate therapies, in line with national guidelines and the latest findings based on medical literature, and without delays or disruptions in patient care.

- Recommendation: We encourage the administration to continue to explore solutions that address drug costs and value to patients instead of complicated and burdensome changes to the provider reimbursement system that result in limited patient access to drugs.

The ASP-Based Part B Reimbursement System Avoids the Gross-to-Net Bubble; Why Create this Issue in Part B?

²³ <https://www.communityoncology.org/portfolio-items/2018-coa-practice-impact-report/>

²⁴ <https://www.communityoncology.org/pdfs/Trends-in-Cancer-Costs-White-Paper-FINAL-20160403.pdf>

- Response: In Part B, the ASP price is already the net price – it includes discounts and rebates both in Medicare and beyond, and therefore it reflects the competitive dynamics in the marketplace. This system avoids the “gross to net bubble,” which in Part D leads to opaque rebate amounts and higher patient OOP costs. Furthermore, in Part D, patient cost-sharing is based on prices that do not account for discounts and rebates. Moving drugs from Part B to Part D would introduce this lack of transparency and higher patient cost-sharing into Part B, where it currently does not exist.

Negotiating Power Already Exists in Part B Through Organized Buying Groups.

- Response: The stated goal of exploring policies like a Part B to Part D shift – or alternative distribution models, such as CAP – is to improve negotiating power. However, oncology drugs already have very consolidated buyers in Part B that help reduce costs for patients and providers, in the form of group purchasing organizations (GPOs). It is estimated that more than 95% of distribution in oncology flows through a handful of GPOs that facilitate better pricing through volume and market share-based incentive contracts. Furthermore, oncology GPOs can serve as a clearinghouse of important utilization and outcomes data that will be vital in the broader context of moving towards health care focused on patient value. Adding another entity to the supply chain, particularly PBMs who have conflicting incentives, is highly unlikely to add any added benefit in terms of competition or negotiation.

Part B Growth Is Disproportionately Driven by Hospital Outpatient Departments (HOPDs), so Reform Proposals Should Not Target Community Providers.

Concern over spending growth in Part B is totally unfounded and misrepresented. It is not the drug purchasing model utilized by community oncology practices and other Part B providers that has caused Part B drug spending growth, but rather increased drug spending by HOPDs, which have higher costs and higher drug utilization rates than other settings of care. In fact, a study from The Moran Company on drug cost trends in Part B found that volume-weighted ASP for all drugs has actually remained steady year over year from 2007 to 2017; ranging from \$5.79 in the fourth quarter of 2007 to \$7.56 in the fourth quarter of 2017. For oncology drugs specifically, the volume-weighted ASP of oncology drugs stayed consistent with medical inflation from 2007 to 2017.²⁵ This means that Part B drug prices have remained relatively flat and thus are not a significant driver of increased spending in Part B.

Meanwhile, for over a decade, economic pressures have led oncologists to sell their practices to hospitals, and shift care from community practices to HOPDs. Services provided in HOPDs typically have the highest payment rate. For a new evaluation and management (E&M) visit, average payments for a 7-day episode following a new visit in HOPDs are 29% higher than in a physician office.²⁶

According to MedPAC, Part B drug spending has been growing more rapidly for HOPDs than for physicians and suppliers. Between 2009 and 2015, Part B drug spending grew at an average annual rate of 15.9% for HOPDs and 6.4% for physicians and suppliers. Moreover, MedPAC found that over half of Medicare Part B drug spending in HOPDs in 2015 was attributable to hospitals that participate in the 340B drug pricing program and purchase drugs at sharply discounted prices.²⁷

- Recommendation: Higher costs and utilization of drugs and services in HOPDs, combined with increasing use of HOPDs for treatment due to provider consolidation, are driving spending in Part B. Policy solutions should be focused on the real problems with HOPDs, and in particular 340B hospitals that leave patients with high OOP costs, rather than on the misguided fixation with the current Part B distribution system in independent community oncology practices, which has proven to be both effective in providing just-in-time cancer treatment and extremely cost efficient.

²⁵ <http://phrma-docs.phrma.org/files/dmfile/PhRMA-ASP-Trend-Report-final-02212018.pdf>

²⁶ Ibid.

²⁷ http://www.medpac.gov/docs/default-source/data-book/jun17_databooksec10_sec.pdf

We applaud the administration for already implementing important changes to drug reimbursement for 340B hospitals, but we think there is more to be done to level the playing field between physicians and hospital practices.

LOWER DRUG PRICES

Increasing Medicare Part D plan flexibility

With few therapeutic and generic alternatives available in cancer treatment, access to innovative life-saving treatments is vital. We are concerned that giving PBMs greater flexibility in designing formularies will not lower drug prices, but rather will restrict treatment choices for patients, especially if there are any changes to cancer's status as a "protected" class.

Medicare Part D formularies are already restrictive in terms of drug coverage and tiering placement. An analysis of 2018 formularies shows that the majority of prescription drug plans (PDPs) and Medicare Advantage Prescription Drug plans (MA-PDs) use 5-tier formularies, while the rest use 6-tier formularies.²⁸ In PDPs, 62% of drugs are covered on coinsurance tiers, which makes OOP costs for patients more variable and less predictable. In 2018, for the second consecutive year according to an Avalere analysis, many of the top 10 PDPs by enrollment covered fewer drugs than during the prior year.²⁹ Both PDPs and MA-PDs cover the majority of Part D drugs with some form of utilization management.

For classes of medications that treat some of the most complicated conditions and diseases, including cancer, beneficiaries have for years enjoyed extra protections under the Medicare drug benefit. Medicare's "six protected classes" policy has long stood as a guarantee to patients that their access to whatever medication their doctor chooses for them will never be in doubt. Consequently, extending Part D plan flexibilities to drug classes that currently have protected status would have very negative consequences for patients. Cancer is a highly sensitive therapeutic area and providers should be allowed to choose the most clinically appropriate therapies for their patients without facing additional hurdles.

PBM-dictated restrictions are already causing many patients extreme difficulty, lengthy delays, and unacceptable denials in accessing their life-saving anti-cancer drugs. COA has highlighted a number of PBM horror stories in a series of papers.³⁰ With the growing control and influence of PBM middlemen on cancer patient's treatment, there is an endless supply of PBM horror stories and COA has more compilations on the way. Here are a few real patient stories from the most recent papers. (Names have been changed to protect patient privacy):

James, a 73-year old husband, father, and grandfather battling metastatic non-small cell lung cancer, was prescribed a new medication. His physician submitted a prior authorization request to the PBM, which was denied because the PBM demanded the results of James' blood tests for jaundice – a request that made no sense. James' physician waited in vain for the determination for the next 3 weeks, only to be disconnected or told to call back when he called to check on the status. Unfortunately, James passed away just a few weeks after the initial request, losing the chance to see if the medicine would have prolonged his life.

Liane submitted a prescription to her PBM's preferred specialty pharmacy only to be notified that her insurance company required a new prior authorization in addition to the one she had already received. The insurance company did not tell her this until the day she was scheduled to begin treatment, so her treatment was delayed unnecessarily. A week later,

²⁸ <https://360.avalere.com/system/files/20171109%20-%20Policy%20360%20Perspective%20-%20Avalere%20Analysis%20of%202018%20Part%20D%20Formularies..pdf>

²⁹ <https://360.avalere.com/system/files/20171109%20-%20Policy%20360%20Perspective%20-%20Avalere%20Analysis%20of%202018%20Part%20D%20Formularies..pdf>

³⁰ <http://bit.ly/pbmstoriesv1> , <http://bit.ly/pbmstoriesv2> , <http://bit.ly/pbmhorrorstoriesv3>

Liane found out it could take another seven business days or more to receive a decision. Once the approval was granted, it took another 2 days for the specialty pharmacy to receive the prescription, and another day to process it, totaling nearly 3 weeks from the date of the original prescription before Liane began her treatment.

Charlene, a 67-year old bone cancer patient, is currently in limbo as she copes with her illness. She has already endured a double mastectomy in response to metastatic breast cancer. More than eight weeks ago her oncologist prescribed Ibrance for the retired secretary, who is married to a retired Air Force Master Sergeant (who has had problems of his own with PBMs). The community oncology practice could have filled the prescription the same day in-house but was required to send it out to Charlene's PBM mandated pharmacy. But the multi-billion-dollar, Fortune 100 PBM sat on the doctor's orders for a month, and then refused to fill the prescription. Charlene could pay out of pocket, but she and her husband are on a fixed income. And why should they when they have Tricare and Medicare? If the PBM followed doctor's orders, she would be billed only \$24 for a three-month supply, and she would now have the prescribed Ibrance to make her more comfortable.

- Recommendation: We urge HHS to consider the real patient faces and care experience behind each prescription and the growing negative impact that PBM middlemen have on their care when making decisions about access to medications for our seniors. The administration's blueprint seeks to put "American patients first" and granting PBM middlemen corporations more power and influence will fly in the face of that goal.

Role of rebates and PBMs

As we outline above, COA is very concerned about how PBM incentives over time have added access challenges for patients without containing costs for the government or the health care system. We believe these entities have introduced new, often hidden, fees that have raised costs, created complex bureaucracies that have often denied patients access to necessary medications, and limited patients' access to certain pharmacies that were not affiliated with a PBM. COA commends the administration for their interest in exploring the role of PBM middlemen on drug prices and the supply chain.

PBMs are contracted by insurance carriers to negotiate on their behalf with pharmaceutical companies. These middlemen corporations have quietly become an unavoidable, multibillion dollar behemoth part of our nation's health care system. Due to the convoluted and opaque nature of PBM contracts, savings from rebates are often not passed on to lower the price of prescriptions for patients but instead serve to increase PBM profit margins. The result is that patients are stuck paying the full, inflated list price on medications, even though their health plan has received discounts and never paid that list price.

The largest three PBMs now control at least 80% of drug benefits for over 260 million Americans and have the power to negotiate drug costs, what drugs will be included on plan formularies, and how those drugs are dispensed. Oftentimes, patients are required to receive drugs through PBM-owned specialty pharmacies.

In theory, PBM consolidated negotiating power should be translated into lower costs for beneficiaries and payers, but there is little evidence of that. On the contrary, percentage-based rebates for PBMs and DIR (direct and indirect remuneration) fees obtained from pharmacy providers distort incentives to keep drug prices low. We note that list prices for oral cancer drugs have in cases increased tremendously such as Revlimid (64%), Stivarga (52%), and Afinitor (59%).

Furthermore, PBMs restrict pharmacy networks and patients' ability to obtain drugs directly from dispensing providers. Last but not least, as originally contemplated by CMS, DIR Fees were supposed to provide pharmacy providers with additional reimbursement based on certain quality performance metrics. Instead, DIR Fees have been used by PBMs to claw back additional funds at the expense of Medicare and beneficiaries.

- Recommendation: COA strongly supports measures to ensure that the savings that PBMs negotiate are passed along to patients at the point-of-sale. PBMs have been secretly reaping the benefits of discounts and rebates at the expense of cancer patients for too long. COA also supports any efforts by HHS or Congress to introduce

greater transparency and accountability for PBMs and limiting their ability to deny cancer patients access to vital medications.

Facilitating value-based purchasing (VBP) arrangements, including indication-based pricing

COA is committed to increasing the quality of cancer care and decreasing costs, for both drugs as well as hospital-related costs, the biggest driver of cancer treatment spending. COA believes in and supports value-based models that can positively impact prices and utilization and we applaud the administration for its interest in removing regulatory barriers to outcome-based care. We have seen important FDA activity that would support value-based pricing for drugs, as well as a request for information (RFI) seeking input on ways to reduce the burdens associated with the Stark Law.

COA has long been working with the rest of the oncology community to spearhead innovative payment reform aimed to lower the costs and improve the quality of cancer care. An important example of these efforts is the CMS Innovation Center's oncology payment and delivery reform initiative, the Oncology Care Model (OCM), which we are proud to have helped shape and support.

We are currently working on important innovative thinking around a universal model of oncology payment reform building on the OCM. COA and its member practices are now devoted to seeking solutions using data and the real world medical experience of physicians, nurses, administrators, and others to craft viable, patient-centric solutions. Our efforts around an "OCM 2.0" aim to address several issues identified by current participants, and how value-based payments might be incorporated in the future. For example, we are working with providers and other stakeholders to define how to include innovative therapies and how to determine opportunities for cost savings without penalizing providers for appropriately prescribing needed medications. We also believe that value-based pricing for drugs, including outcome-based and indication pricing, which the current system does not adequately support, should be a reform priority and can positively impact both prices and utilization.

As with the OCM, thoughtful and effective value-based initiatives must adequately engage stakeholders, including patients and physicians, in an open, transparent, and constructive dialogue. COA is very open to further engagements on value-based approaches to all facets of cancer care, including both drugs and services, and we want to ensure that cancer care transformation, while costly and labor-intensive for community providers, is *appropriately* incentivized and reimbursed.

CONCLUSION

Summary Recommendations: Priority Areas of Focus and Possible Solutions to Drug Pricing

- **Competition is an essential first step in lowering drug prices.** In cancer treatment, there are currently very few situations where there are lower-priced therapeutic brand name or generic-to-brand substitutes, where there are no side effect considerations or other issues that dictate drug choice. Decreasing research and FDA filing costs, time, regulations, and other impediments, including roadblocks by brand name drug manufacturers, in getting competitive brand name, generic, and biosimilar competitors to market is a necessary first step to lowering drug prices.
- **Biosimilars need to be a focus, from approval through physician acceptance.** As we noted, biosimilars are an important factor in fostering increased competition to lower drug prices. We have several plans to educate oncologists on biosimilars and to spur their acceptance when these less expensive, but therapeutically equivalent, drugs are available. We repeat that COA is ready to work with the FDA and HHS/CMS in fostering the adoption of biosimilars, including examining ways to tweak the Part B reimbursement system.
- **The scope and magnitude of discounts and rebates need to be reduced.** The drug distribution system is overwhelmed with excessive mandatory discounts and rebates, including 340B and PBM rebates, that are fueling drug prices. As these discounts and rebates are increasing in scope and magnitude, manufacturers continue to factor those into their list prices, fueling a continuous spiral of ever growing costs. We applaud the

actions of HHS/CMS to date to fix 340B in hospitals and the proposal to tie 340B discounts to charity care provided by hospitals. Additionally, we agree with the proposals to limit, or even eliminate, after-sale rebates and to ensure that patients are paying for their medications based on “net” prices, not inflated “list” prices.

- **Universal site payment parity is essential, including with dedicated cancer hospitals with special Medicare exemptions.** Hospitals cost Medicare and private insurers, and their beneficiaries, more for treating cancer patients. As noted earlier in the letter, COA believes there needs to be site payment parity whereby the same services are paid at identical rates, regardless of the site-of-care – hospital or independent oncology practice. Also, there should be no special Medicare exemptions for dedicated cancer hospitals.
- **Focus on the OCM 2.0.** As noted above, COA is developing a universal payment model for cancer care, *including value-based payment for services and drugs*. Because of barriers to value-based contracting, including Medicaid best price and ASP, CMS will have to provide waivers for pharmaceutical companies to implement value-based agreements. Our effort on the OCM 2.0, based on value-based payments for both drugs and services, is the type of constructive effort we would like to work with HHS, CMS, and the Innovation Center on — and are most willing to do so.

COA appreciates the opportunity to provide insight and comments to HHS on the RFI. We are dedicated to lowering the escalating and unsustainable cost of cancer care, including lowering cancer drug prices and costs, and look forward to working closely with policymakers on thoughtful reforms that benefit patients and taxpayers. **We are available immediately to meet with HHS/CMS, including the Innovation Center, to discuss in detail these recommendations, especially the OCM 2.0 and the inclusion of value-based payment for drugs and services.**

Independent community oncology providers have deep expertise and insight that can help with shaping and implementing these proposals. Our practices have been active in pioneering oncology payment reform for years and are now working on the next-generation, value-based models that include payment for cancer drugs based on value to patients and the health system. We look forward to serving as a resource for the administration going forward.

We can be contacted through the COA offices if there are any questions about these comments.

Sincerely,



Jeffrey Vacirca, MD
President



Ted Okon
Executive Director