July 16, 2018

*via electronic submission*

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

**Re: RIN 0991-ZA49; HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs; Request for Information (RFI)**

Dear Secretary Azar:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to respond to the Request for Information (RFI) pertaining to the Department of Health and Humans Services' (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

Approximately 1.7 million new cancer cases are expected to be diagnosed in 2018.[1] Age is one of the most important risk factors for cancer, with one half of cancer cases occurring in people over the age of 65.[2] Therefore, the rates of cancer have a profound fiscal impact on the Medicare and Medicaid programs and the beneficiaries these programs serve. We also recognize that some of the policies considered in the RFI could have implications beyond Medicare and Medicaid – affecting patients who have private insurance or who are uninsured.

Drug therapies play an integral role in cancer treatment. Advances in research have improved our understanding of cancer at the molecular level – leading to the development of more precise detection and diagnostic tools and corresponding therapies that are able to more specifically attack cancer. Over the course of the last few years there has been a remarkable increase in the number of new cancer drug therapies. In 2017, 15 out of the 45 new therapies approved by the Food and Drug Administration (FDA) were for cancer.[3]

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[1] American Cancer Society, *Cancer Facts and Figures* 2018, https://www.cancer.org/research/cancer-factsstatistics/all-cancer-facts-figures/cancer-facts-figures-2018.html.
[2] National Cancer Institute, *Age and Cancer Risk*, April 29, 2015, https://www.cancer.gov/about-cancer/causesprevention/risk/age.
[3] HBM Report, *Trends in US New Drug Approvals,* January 2018, http://www.hbmpartners.com/media/docs/industry-reports/HBM-Partners-Report-Trends-in-FDA-New-DrugApprovals-2008-2017.

Both cancer patients and survivors rely on drug therapies to treat their disease and prevent recurrence. As more innovative therapies become available, we need to make sure that patients who are likely to benefit from these advances can also afford them so that we can achieve the national goal of eliminating death and suffering from cancer. The inherent challenge will be balancing the need to incentivize continued development of new cancer drugs with greater affordability of these therapies. We commend the Administration for reaching out to all stakeholders to begin a dialogue about ways to achieve this balance, and welcome the opportunity to discuss our policy positions in more detail. Our comments focus on several specific issues included in the RFI.

**Moving Prescription Drugs from Medicare Part B to Part D**

The RFI seeks comment on the feasibility and advisability of moving coverage of prescription drugs currently covered in the Medicare Part B program to the Part D program.

Under the current Medicare program several categories of drugs "incident to" physician services are covered under Part B. These include: some antigens, injectable osteoporosis drugs, erythropoiesis stimulating drugs, blood clotting factors, oral end stage renal disease drugs, cancer medications, parenteral and enteral nutrition, nebulizers, immunosuppressives, intravenous immune globulin, and vaccines.[4] Historically, coverage was provided under Part B because these medications are generally administered by a physician on an outpatient basis – not self-administered by a patient – and therefore should be reimbursed under the physician component of Medicare. As the Department considers whether to move coverage of drugs from Part B to Part D, we urge you to carefully consider – for each drug – the potential impact this change could have on the program and on beneficiaries.

*Safety Concerns:* Beneficiaries enrolled in Part D plans generally get their medication at the local pharmacy or receive the drug through a mail order program. Yet this approach may not be appropriate for many cancer drugs. The drugs used to treat cancer often require special handling – for example controlled temperatures or administration within a specified time-period. Depending on the specific drug, additional physician services, such as bloodwork or a physical exam, may also be medically indicated.

If cancer drugs were moved to Part D, it is unclear how the Medicare program would ensure the proper handling of these medications. We would be concerned with any policy that would require beneficiaries to bear the responsibility for maintaining the proper temperature of the drugs until the drugs could be delivered to the physician's office. Such a policy would constitute an unnecessary burden, particularly if beneficiaries have to make additional trips to the pharmacy and their physician's office prior to infusion. Cancer patients often struggle with transportation issues which would be exacerbated under this policy.

*Increased Patient Costs*: For persons with cancer, the costs associated with treatment are staggering. In 2014, cancer patients (Medicare and non-Medicare) paid $4 billion out-of-pocket for care.[5] Cancer

[4] Centers for Medicare & Medicaid Services, *Prescription Drugs (Outpatient)*, https://www.medicare.gov/coverage/prescription-drugs-outpatient.html.

[5] American Cancer Society Cancer Action Network. *The Costs of Cancer: Addressing Patient Costs*, April 2017, www.acscan.org/costsofcancer.

patients enrolled in Medicare have sizable costs including coinsurance, deductibles, the cost of drugs once they reach the coverage gap and coinsurance after they reach the catastrophic threshold, as well as all costs for uncovered services. These out-of-pocket costs are in addition to premiums most patients pay for Medicare and/or for supplemental coverage – which in some cases can be multiple hundreds of dollars every month.[6] Any change in cost sharing obligations has a profound impact on beneficiary out-of-pocket costs and the affordability of care.

Moving the coverage of cancer drugs from Medicare Part B to Part D has several implications for beneficiary spending. A 2011 study by Acumen, LLC found that shifting oral anti-cancer and anti-nausea drugs from Part B to Part D lowered total per beneficiary costs for Medicare but increased annual beneficiary out-of-pocket costs by nearly $400.[7] It is important to note that these costs only include direct healthcare expenditures, and do not capture the indirect costs, such as transportation and other costs. Moreover, the average Medicare beneficiary maintains a modest income – half of all Medicare beneficiaries have incomes of less than $26,200.[8]

*Patient Illustration*: To illustrate how shifting cancer drugs from Part B to Part D could affect beneficiary out-of-pocket spending, ACS CAN created two common patient treatment scenarios for Stage I breast cancer and Stage IV lung cancer. Working with American Cancer Society medical experts, we identified typical drug regimens for these two diagnoses. The scenarios include drugs currently covered under Medicare Part B and Part D. This analysis is limited only to drugs that would be provided to the patient for cancer care, though we recognize that most beneficiaries would be taking additional prescription drugs related to other conditions. Analysts at Avalere simulated the total healthcare costs and patient out-of-pocket costs for these patients' care if their Part B drugs were to move to coverage under Part D.

In both cases, the changes in out-of-pocket costs differed based on whether the patient had purchased individual private Medigap coverage. For the lung and the breast cancer patients who had Medigap coverage, shifting drugs from Part B to Part D caused significant increases in annual out-of-pocket costs for cancer treatment.[9] This was primarily because Medigap policies provide coverage for beneficiary cost-sharing related to costs incurred under Part A and Part B (to varying degrees depending on the plan). Medigap plans do not cover any cost-sharing related to Part D. For purposes of this analysis, we assumed the beneficiary was enrolled in Medigap Plan F - the most popular plan option.

*Policy Impact for Beneficiaries with Medigap*: In the breast cancer scenario, the out-of-pocket costs for the patient with Medigap would increase from $2,723 to $4,478 if her drugs were shifted to Part D coverage. This is a $1,755 or 64 percent increase in costs.

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[6] Id.

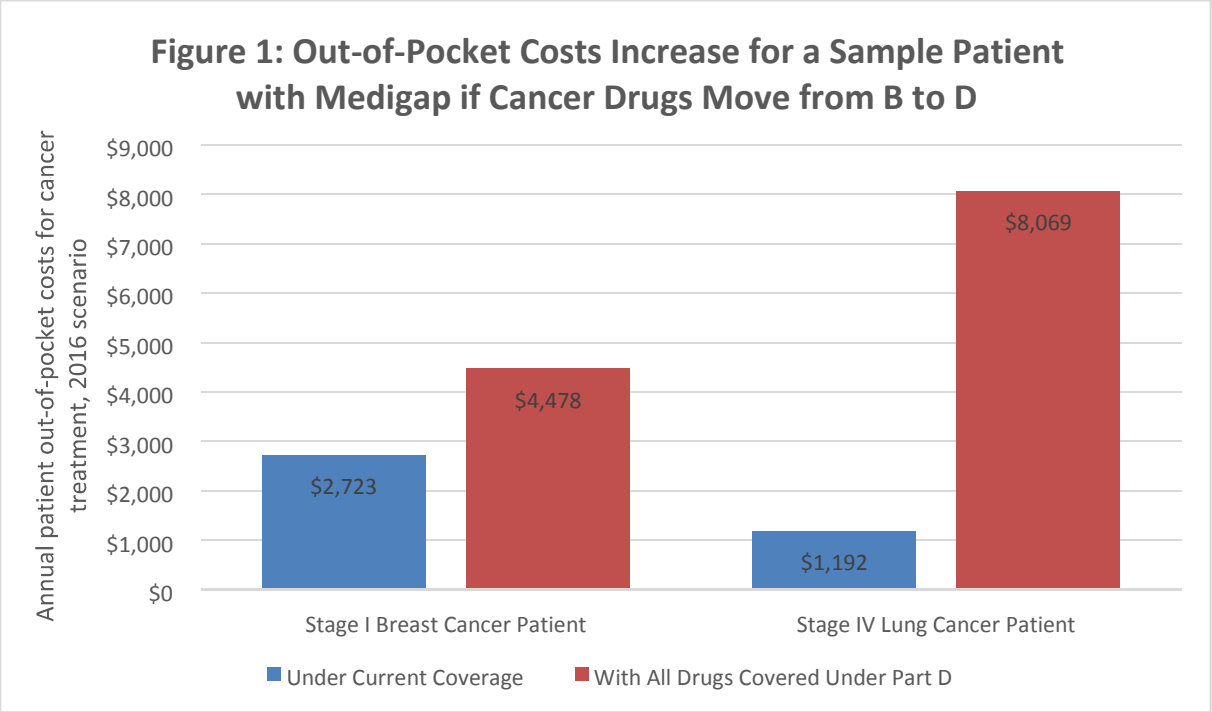
[7] Marrufo G, Rusev E, Piccinini K, Coombs E, Ueda K, Schecter E, *Estimating the Effects of Consolidating Drugs under Part D or B,* September 2011, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trendsand-Reports/Reports/downloads/Acumen_B_to_D_Final_Report_2011.pdf.

[8] Jacobson G, Griffin S, Neuman T, and Smith K, *Income and Assets of Medicare Beneficiaries, 2016-2035*, Kaiser Family Foundation, April 21, 2017, https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicarebeneficiaries-2016-2035/.

[9] Analysis only includes costs for cancer treatment. Amounts are based on the 2016 Medicare benefit, 2016 Medigap Policy F, and a specific, popular 2016 Medicare Part D plan. As of January 2, 2020, new enrollment in Plan F will be suspended but currently the plan has the highest enrollment.

The impact is even greater in the lung cancer scenario, which involves several months' treatment with immunotherapy. In this scenario, out-of-pocket costs for the patient with Medigap would increase from $1,192 to $8,069 if his drugs were shifted to Part D coverage. This is a $6,877 or 577 percent increase in costs (See Figure 1 below).

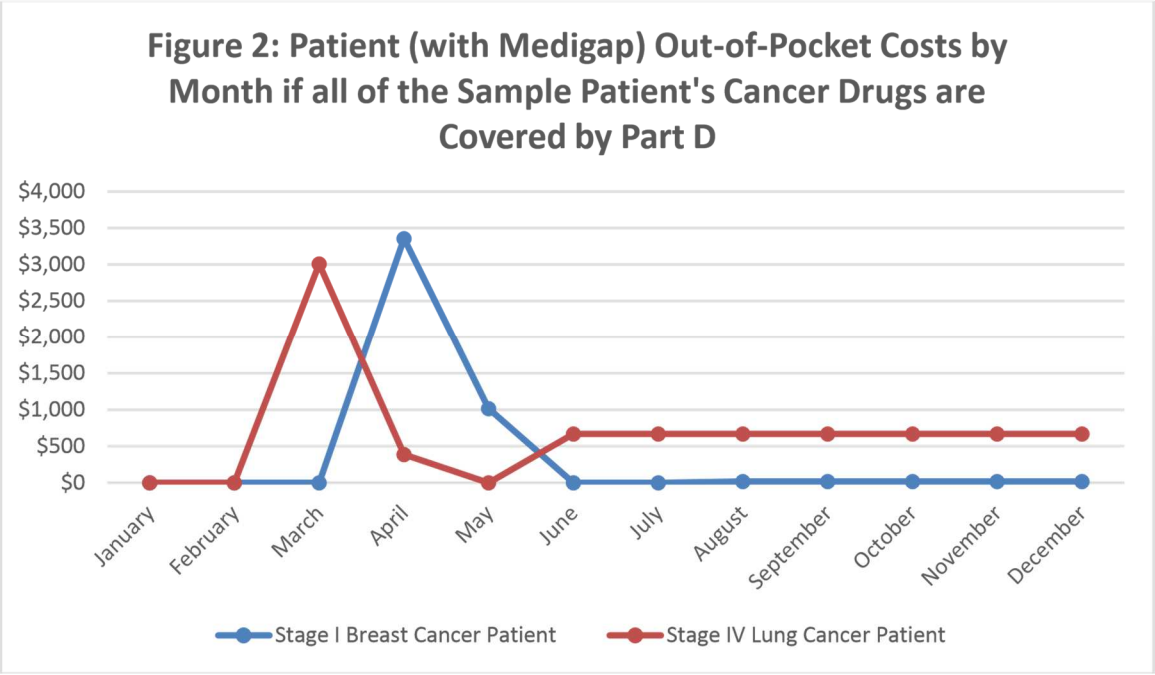
These additional costs would likely be unaffordable, particularly for the majority of beneficiaries who have incomes at or below 200 percent of the federal poverty level,[10] and who likely have other noncancer-related healthcare costs as well.




Source: Avalere analysis of 2016 direct cancer healthcare expenditures, based on patient costs scenarios from ACS CAN publication, *The Costs of Cancer: Addressing Patient Costs*, www.acscan.org/costsofcancer. Costs do not include premium payments. Assumed formulary tier placement: medical-benefit generics with costs under $100/cycle on tier 2 (generic drugs tier), medical-benefit generics with costs of $100$1,000/cycle on tier 3 (preferred brand tier), and all brand medical-benefit drugs, each over $3,000/ cycle, on tier 5 (specialty).

The majority of costs in the breast cancer scenario are concentrated in two months during which the patient is receiving chemotherapy treatment. In the lung cancer scenario, spending also spikes during the first month the patient receives chemotherapy. In both cases the patients are expected to pay over $3,000 in out-of-pocket costs in one month (See Figure 2 below). The fact that such significant costs would be imposed over a limited period of time presents an additional burden on beneficiaries, who would need to provide their cost-sharing payment in advance of receiving their drug from a pharmacy or provider.

[10] Jacobson G, Griffin S, Neuman T, and Smith K, *Income and Assets of Medicare Beneficiaries, 2016-2035,* Kaiser Family Foundation, April 21, 2017, https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicarebeneficiaries-2016-2035/.

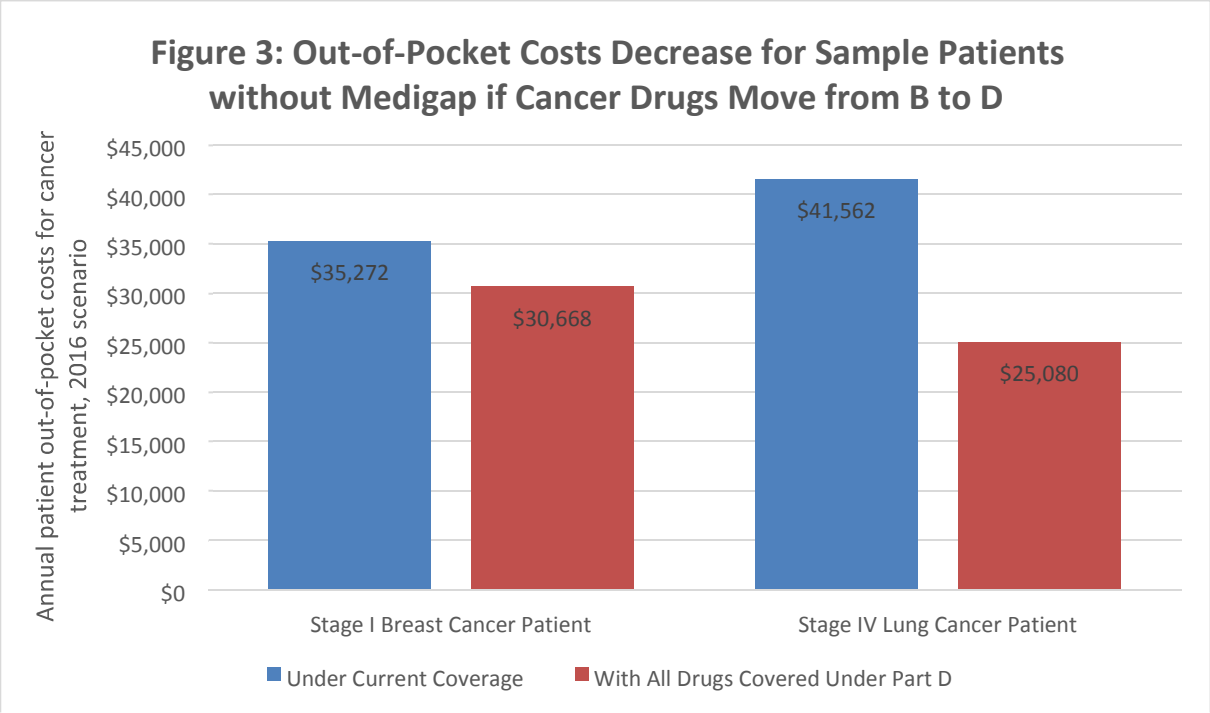



Source: Avalere analysis of 2016 direct cancer healthcare expenditures, based on patient costs scenarios from ACS CAN publication, *The Costs of Cancer: Addressing Patient Costs*, www.acscan.org/costsofcancer. Costs do not include premium payments. Assumed Part D formulary tier placement: medical-benefit generics with costs under $100/cycle on tier 2 (generic drugs tier), medical-benefit generics with costs of $100$1,000/cycle on tier 3 (preferred brand tier), and all brand medical-benefit drugs, each over $3,000/cycle, on tier 5 (specialty).

*Policy Impact for Beneficiaries without Medigap:* For the breast and lung cancer patients without Medigap or supplemental coverage, costs would decrease if cancer drugs were shifted from Part B to Part D.[11] In the breast cancer scenario, out-of-pocket costs for the patient without Medigap would decrease from $35,272 to $30,668 if her drugs were shifted to Part D coverage. This is a $4,604 or 13 percent decrease in costs.

Once again, the difference is more pronounced in the lung cancer scenario, where the patient without Medigap would have out-of-pocket costs decrease from $41,562 to $25,080 if his drugs were shifted to Part D coverage. This is a $16,481 or 40 percent decrease in costs (See Figure 3).

[11] This analysis only includes costs for cancer treatment. Scenarios only include direct healthcare expenditure, and do not capture the indirect costs of cancer, such as transportation, housing and childcare costs.




Source: Avalere analysis of 2016 direct cancer healthcare expenditures, based on patient costs scenarios from ACS CAN publication, *The Costs of Cancer: Addressing Patient Costs*, available at www.acscan.org/costsofcancer. Costs do not include premium payments. When determining Part D formulary tier placement of drugs previously covered under Part B are based on, Avalere assigned tiers based by placing medical-benefit generics with costs under $100/ cycle on tier 2 (generic drugs tier), medical-benefit generics with costs of $100-$1,000/ cycle on tier 3 (preferred brand tier), and all brand medical-benefit drugs, each over $3,000/ cycle, on tier 5 (specialty).

Before implementing any changes to Medicare coverage of cancer drugs, HHS must give serious consideration to the consequences for beneficiaries in both scenarios. Moving drugs from Part B to Part D coverage will have varying degrees of impact, depending on the beneficiary's source of supplemental coverage, if any. Approximately 16 percent of Medicare beneficiaries have no supplemental coverage of any kind.[12] Of beneficiaries who are enrolled in traditional Medicare, approximately 27 to 30 percent have some type of Medigap plan.[13] And as the data above suggests, these beneficiaries will be most likely to experience higher out-of-pocket costs if their prescription drugs were moved from coverage under Part B to Part D. Further, 12 percent of Part B beneficiaries are not enrolled in a Part D plan or are enrolled in coverage less generous than Part D.[14] For the cancer patients in this group - how would they obtain coverage of their medication?

[12] Medicare Payment Advisory Commission, *Data Book: Health Care Spending and the Medicare Program*, June 2017, http://medpac.gov/docs/default-source/data-book/jun17_databooksec2_sec.pdf?sfvrsn=0.
[13] AHIP Center for Policy and Research, *Trends in Medigap Enrollment and Coverage Options*, 2014, https://www.ahip.org/wp-content/uploads/2016/04/MedigapEnrollmentReport_Linked.pdf.
[14] Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, March 2017, http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf.

*Impact on Part D Program*: Moving cancer drugs to Part D could also create unintended costs, including potentially increasing the average Part D beneficiary premium. An early report to Congress by then HHS Secretary Michael Leavitt found that "[t]o the extent that any of the drugs moved from Part B to Part D are particularly high cost drugs and a particular PDP experiences disproportionate enrollment of beneficiaries who use these drugs, the Part D premium would be higher for all beneficiaries enrolled in that plan."[15]

While the Medicare Part B program does not restrict access to the drugs it covers, Part D plan sponsors have significant leeway in terms of benefit design and determining what drugs are covered under the plan's formulary. Current policy requires Part D plan sponsors to cover all or substantially all drugs within six categories and classes of critical concern (the so-called "six protected classes"), and as noted later in our comments, we are concerned with the Department's proposal to amend this critical protection. The concern is heightened when considering the potential adoption of both the policy change in moving drugs from coverage under Part B to Part D and the elimination of the six protected classes. In such a scenario, beneficiaries may not have coverage for their medically necessary oncology drugs because absent additional protections (which have yet not been proposed by the Department) there would seemingly be no requirement for Part D plans to provide coverage of the panoply of oncology drugs.

Moreover, even if the Department were to mandate that Part D plan sponsors provide coverage of all oncology drugs, we are concerned that these drugs would be placed on the Part D specialty tier. Almost all Part D plans utilize a co-insurance for this tier, which provides the beneficiary with little predictability on actual cost-sharing responsibility, rather than a co-payment that provides more predictability for out-of-pocket costs for the beneficiary.[16] The Centers for Medicare & Medicaid Services (CMS) also allows Part D plan sponsors to impose a coinsurance amount on the specialty tier of up to 33 percent, with most Part D plan sponsors charging either 25 percent or 33 percent.[17] As discussed in detail above, these out-of-pocket costs can be significant, particularly on a population the majority of which have limited incomes.

*Impact on the Medicare Advantage (MA) Program*: It is also worth noting that moving drugs from coverage under Part B to Part D will have significant impact on the MA program. Currently, thirty percent of Medicare beneficiaries are enrolled in a managed care plan[18] and 88 percent of Medicare Advantage plans provide prescription drug coverage.[19] Moving drugs from coverage under Part B to Part

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[15] Leavitt, Michael O., Report to Congress, *Transitioning Medicare Part B Covered Drugs to Part D*, 2005, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/RtC_PtbtoPtD_2005_4.pdf.

[16] Cubaniski J, Damico A, Hoadley J, Orgera K, and Neuman T, *Medicare Part D: A First Look at Prescription Drug Plans in 2018*, Kaiser Family Foundation, October 13, 2017, https://www.kff.org/report-section/medicare-part-d-afirst-look-at-prescription-drug-plans-in-2018-findings/.

[17] Id.

[18] Medicare Payment Advisory Commission, *Data Book: Health Care Spending and the Medicare Program*, June 2017, http://medpac.gov/docs/default-source/data-book/jun17_databooksec2_sec.pdf?sfvrsn=0, at page 25.

[19] Kaiser Family Foundation, *Medicare Advantage,* October 10, 2017, https://www.kff.org/tag/medicare-advantage/.

D will significantly alter the benefit structure of these plans. Many Medicare Advantage plans have an annual limit on beneficiary out-of-pocket spending for in-network services covered under Part A and Part B. If prescription drugs were moved from coverage under Part B (where MA enrollees enjoy some protection[20]) to coverage under the Part D program (where no such protection exists in the MA program), even MA enrollees could see their out-of-pocket costs increase, similar to the expected increases borne by beneficiaries in traditional Medicare, as discussed in detail above.

**Potential Changes to the Six Protected Drug Classes**

HHS suggests that in response to President Trump's call to action, it may support better negotiation by "[p]roviding plans full flexibility to manage high cost drugs that do not provide Part D plans with rebates or negotiated fixed prices, including in the protected classes."[20]

ACS CAN supports efforts to reduce beneficiaries' cost-sharing for high-cost drugs. However, we are concerned that the Administration's proposal has the potential to limit beneficiary access to prescription drugs in the classes of clinical concern (e.g., the "six protected classes"). We strongly urge the Administration not to adopt this proposal.

*Six Protected Classes Established Since the Beginning of the Part D Program*: Since the program's inception, CMS has required all Part D plan sponsors to cover all or substantially all drugs within the following categories and classes: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants. CMS created the six protected classes policy to ensure that beneficiaries who needed these drugs would have access to them. In fact, CMS' current Medicare Prescription Drug Policy manual clearly states that "CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[21]

*Six Protected Classes Policy Protects Vulnerable Beneficiaries*: Many of these prescription drugs are not necessarily therapeutically equivalent with products within the same class. For example, within the class of antineoplastics there are multiple subcategories defined by the United States Pharmacopeia (USP). Not only do the drugs within the antineoplastics class vary widely, but variation exists within the USP subcategories. For example, the USP subcategory of tyrosine kinase inhibitors has been developed to treat cancer, but each drug within this category may target a different mutation that is relevant to a small subcategory of patients with a given disease. This targeting means that restricting formularies to single drugs within a USP subclass would necessarily leave out many unique drugs that would treat distinct cancers.

Some beneficiaries may have to try different drugs within one class before it is possible to determine the most optimal drug for their condition. Beneficiaries may also have co-morbidities requiring very nuanced treatment regimens. For example, one fourth of cancer patients have a diagnosis of clinical

[20] Fed. Reg. at 22695.

[21] Centers for Medicare & Medicaid Services, *Medicare Prescription Drug Benefit Manual*, Ch. 6 – Part D Drugs and Formulary Requirements, sect. 30.2.5.

depression.[22] Ensuring broad access to drugs within these classes also prevents Part D plan sponsors from designing its formulary in such a way as to discourage beneficiaries with certain conditions from enrolling in their plan.

If the six protected classes policy was eliminated, Part D plans would be permitted to exclude some of the drugs included in the classes. If a drug were no longer covered under the Part D plan's formulary, the beneficiary could file an appeal to obtain coverage for the drug. However, stakeholders have noted various issues with the Part D appeals and exceptions process,[23] which is complex and multi-leveled.[24] We are concerned that this alternative could result in beneficiaries simply choosing not to fill the prescription, which could lead to poorer health outcomes and higher program costs.

*Part D Plans Already Have Flexibility*: While Part D plan sponsors are not currently permitted to remove a drug within the six protected classes from its formulary, sponsors may tier these drugs on their plans' formularies – therefore giving plan sponsors some leverage in price negotiations. Suggesting that the Administration would curtail a policy that was instituted to protect the most vulnerable beneficiaries seems an inappropriate response to plan requests for greater leeway to negotiate lower prices for drugs within the six protected classes.

Part D plans already have more restrictive formularies for drugs covered under the six protected classes relative to commercial plans, suggesting that the current policy does not prevent Part D Plan sponsors from effectively managing formularies within these drug classes.[25] Further, generic utilization for drugs within the six protected classes is higher than other drug classes (92 percent versus 84 percent).[26]

*Eliminating Six Protected Classes Policy Could Increase Program Costs*: Even setting aside the negative impact on beneficiaries who rely on this valuable protection, eliminating the six protected classes designation could likely increase Part A or Part B costs. If beneficiaries are unable to access the prescription drugs most medically appropriate for their condition, they will likely incur higher costs elsewhere in the program, such as additional physician services or emergency room utilization.

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[22] American Cancer Society, *Coping with Cancer: Anxiety, Fear, and Depression,* https://www.cancer.org/treatment/treatments-and-side-effects/emotional-side-effects/anxiety-feardepression.html.

[23] Medicare Payment Advisory Commission, Report to Congress: *Medicare Payment Policy March 2018*; *The Medicare Prescription Drug Program (Part D) Status Report*, http://www.medpac.gov/docs/defaultsource/reports/mar18_medpac_ch14_sec.pdf.

[24] Medicare Payment Advisory Commission, *The Medicare Prescription Drug Program (Part D) Status Report*, Online Appendixes, http://www.medpac.gov/docs/defaultsource/reports/mar18_medpac_ch14_appendix_sec_rev0618.pdf?sfvrsn=0.

[25] Id.

[26] The PEW Charitable Trusts, *Policy Proposal: Revising Medicare's Protected Classes Policy*, March 2018, http://www.partdpartnership.org/files/resources/DSRI_Policy_Proposal_Revising_Medicares_Protected_Classes_Policy.pdf.

Finally, we note that CMS considered implementing significant changes to the Part D six protected classes in 2014,[27] but ultimately declined to adopt the policy due to overwhelming stakeholder concern.[28]

**Incentives to Lower or Not Increase List Prices**

The RFI solicits feedback on whether drug manufacturers who have increased their prices over a particular period or have not provided a discount should be allowed to be included in the protected classes.[29]

ACS CAN urges HHS not to pursue this policy. As noted above, the six protected classes policy has been in place since the inception of the Part D program. Beneficiaries have no control over pricing decisions made by a pharmaceutical manufacturer. Yet under the Administration's proposal, they would be harmed by these pricing decisions. Penalizing a manufacturer by no longer including their product among the six protected classes harms beneficiaries who will be unable to obtain access to these medications that the Department has long recognized are classes of clinical concern.

**Capping Part D Expenses**

Medicare beneficiaries with serious chronic conditions like cancer rely on medication therapies to treat their disease and prevent recurrence. The out-of-pocket costs for these drugs can be significant.

In 2018, Medicare beneficiaries in Part D pay: a $405 deductible, 25 percent coinsurance until they reach $3,750 in total spending at which point they pay 35 percent for brand name drugs and 44 percent for generics until they reach the $5,000 catastrophic threshold, and then a 5 percent copay on further expenditures.[30] As a result of uncapped expenses, one in ten Part D enrollees with high drug costs in 2015 spent at least $5,200 out-of-pocket on their prescription drugs and ten percent of beneficiaries with cancer spent more than $6,000 on average.[31] For many of these beneficiaries there is no financial assistance with high costs. Of the 42.5 million beneficiaries enrolled in Medicare Part D plans in 2017, 30.3 million did not qualify for low-income subsidies (LIS).[32]

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[27] Centers for Medicare & Medicaid Services. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program. Proposed Rule. 79 Fed. Reg. 1918 Jan. 10, 2014.

[28] Centers for Medicare & Medicaid Services. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program. Final Rule. 79 Fed. Reg. 29844 May 23, 2014.

[29] Fed. Reg. at 22698.

[30] Medicare Payment Advisory Commission, *The Medicare prescription drug program (Part D) Status report,* 2018, http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.

[31] Cubanski J, Neuman T, Orgera K, *No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drugs Costs Without a Hard Cap on Spending,* 2017, https://www.kff.org/report-section/no-limit-medicare-part-d-enrolleesexposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending-issue-brief/.

[32] Medicare Payment Advisory Commission, *The Medicare prescription drug program (Part D) Status report,* 2018, http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.

A study using 2012 Medicare claims data found that beneficiaries who use specialty drugs – including cancer drugs – who did not qualify for low-income subsidies (non-LIS beneficiaries) – had higher and variable cost sharing. The study concluded that the existing Part D cost-sharing structure imposes a substantial financial burden for specialty drug users and "implementing both annual and monthly out-of-pocket maximum spending limits would result in lower, more consistent out-of-pocket costs, potentially increasing patients' ability to access treatments for life-threatening, chronic, and rare diseases."[33]

In its March 2018 report to Congress, the Medicare Payment Advisory Commission included in its list of recommendations to improve Medicare Part D the elimination of enrollee cost sharing above the out-of-pocket threshold.[34]

ACS CAN urges the Department to consider working with Congress on ways to limit Part D expenses. Estimates show that Part D enrollees would have collectively saved $1.2 billion in 2015 if Medicare provided a cap on out-of-pocket spending.[35] Not only would a Part D cap make prescription drugs more affordable for beneficiaries with cancer, but it would also provide greater predictability – beneficiaries would know in advance the maximum amount they would have to pay for drugs and could plan accordingly.

**Federal Preemption of Contracted Pharmacy Gag Clause Laws**

One of the reasons individuals purchase health insurance is to protect against high out-of-pocket health care costs – including for prescription drugs. Instead of paying the full or "off-insurance" price at the pharmacy, the patient pays a co-pay or co-insurance amount determined by their insurance plan. There are some instances when the off-insurance price of a drug is lower than the patient's co-pay or coinsurance. The most common example is penicillin, which can have an off-insurance price of $5 – far less than a co-pay of $15.

The RFI asks for information regarding so-called pharmacy "gag clauses," which prohibit pharmacists from informing patients when their prescribed drug could be purchased at a lower price off-insurance. HHS indicated in the RFI, and confirmed with a May 17 letter from CMS Administrator Seema Verma to Part D Sponsors,[36] that Part D plans must ensure enrollees: 1) pay the lesser of the Part D negotiated price (the "off-insurance" price) or copay, and 2) ensure enrollees have access to drug price information.

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[33] Doshi JA, Li P, Pettit AR, Dougherty S, Flint A, Ladage VP, *Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon".* Am J Manag Care. 2017;23(3 Suppl):S39-S45.

[34] Medicare Payment Advisory Commission, *The Medicare prescription drug program (Part D) Status report,* 2018, http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.

[35] Cubanski J, Neuman T, Orgera K, *No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drugs Costs Without a Hard Cap on Spending,* 2017, https://www.kff.org/report-section/no-limit-medicare-part-d-enrolleesexposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending-issue-brief/.

[36] Memorandum from Seema Verma to All Part D Sponsors, *Unacceptable Pharmacy Gag Clauses,* May 17, 2018, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/Other-Content-Types/2018-05-17.pdf.

The letter stated that "any form of 'gag clauses' [are] unacceptable and contrary to our efforts to promote drug price transparency and lower drug prices."[37]

Some state legislatures have passed laws prohibiting plans from using these gag clauses. In the RFI, HHS asks for information regarding "federal preemption of contracted pharmacy gag clause laws." While this language is unclear, we assume HHS is implying it is also considering instituting a federal prohibition of gag clauses in all plan contracts, which would affect privately-insured enrollees as well. We urge HHS to clarify that the agency's intent is to prohibit gag clauses nationwide.

ACS CAN supports the prohibition and removal of pharmacy gag clauses in all contracting between pharmacies, insurance plans, and (where applicable) pharmacy benefit managers. Removing gag clauses will allow pharmacists/pharmacies to have the opportunity to have a more open dialogue regarding questions the patients may have about their prescription drugs. However, these proposals are not likely to address the high cost of some cancer medications, but rather would more likely benefit the patient in cases where he/she is purchasing low-cost, older drugs.

HHS also implies it would like to explore other strategies that might be effective in providing price information to consumers at the point of sale. We are not aware of other evidence-based, proven effective strategies in communicating this information. However, we encourage HHS to explore this further, and invite you to work with ACS CAN and other patient groups on patient focus groups and consumer testing. We urge HHS to conduct rigorous consumer testing on any proposal to ensure that patients are provided the right kind of information and the right amount of information to enable them to make choices that will save money.

**Inform Medicare Beneficiaries with Medicare Part B and Part D About Cost-Sharing and Lower-Cost Alternatives**

The RFI notes that health plans and pharmacy benefit managers have found new ways to inform prescribers and pharmacists, when prescribing or dispensing a new prescription, about the formulary options, expected cost-sharing, and lower-cost alternatives specific to individual patients. The Department seeks input on the extent to which this technology could be used to better inform beneficiaries of lower-cost alternatives.

ACS CAN supports the Department's efforts to provide cancer patients with greater transparency regarding formulary options, expected cost-sharing, and lower-cost alternatives. Studies suggest that more than 50 percent of cancer patients would like to have discussions about the cost of their care with their healthcare providers (i.e., prescribers, pharmacists).[38] However, few healthcare providers (less than 30 percent) are comfortable engaging cancer patients about costs.[39] As a result, the percentage of healthcare providers who report having these conversations with cancer patients remains low, and the

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[37] Id.

[38] Shih T, Chien CR, *A Review of Cost Communication in Oncology: Patient Attitude, Provider Acceptance, and Outcome Assessment, Cancer* 123, 6(2017): 928–939.

[39] Altomare, I. et al, *Physician Experience and Attitudes Toward Addressing the Cost of Cancer Care, J. Oncol. Pract.* 3(2016): 3281-8, 247-8.

quality and contents of these discussions vary significantly.[40,41,42] Healthcare providers most commonly cited lack of resources to easily provide accurate out-of-pocket estimates and reported that they feel like they are unable to help with out-of-pocket costs as barriers to engaging cancer patients.[43]

As the Department moves forward with this initiative, there are barriers that will need to be addressed to improve the quantity and quality of cost discussions between prescribers or pharmacists and cancer patients:

- *Lack of Resources to Easily Provide Accurate Out-of-Pocket Cost Estimates*: A recent survey of physicians found that while 56 percent of respondents thought that cost transparency was a high priority, only 11 percent had access to tools capable of calculating individual patients' out-of-pocket costs.[44] This is due to the complexity of obtaining and calculating patients' responsibilities, which must adjust for insurance benefit design (e.g., deductible, copayment, coinsurance, and out-of-pocket maximums), which differs by type of insurance coverage and across Medicare Part B and Part D.[45] Few tools that can provide this level of detail exist on the market today, and cost may prohibit healthcare providers from accessing these tools. In addition, some providers may be unwilling to engage in such education for fear of running afoul of anti-kickback regulations. Thus, the Department is in the best position to develop such resources and should do so in consultation with stakeholders.
- *Unable to Help with Out-of-Pocket Costs*: Roughly a third of healthcare providers avoid discussing out-of-pocket costs with cancer patients because they believe they are unable to help.[46] However, research suggests that when healthcare providers engage cancer patients about cost, out-of-pocket spending was reduced 57 percent of the time.[47] Providers can help reduce out-of-pocket spending for cancer patients in several ways. While some of these strategies include changes to the care plan (e.g., switching to lower-cost alternatives, changing dosage/frequency), other strategies include changing logistics of care (e.g., identifying which pharmacies were cheaper, writing prescriptions for 90-day supplies to drive down co-pays), facilitating co-pay assistance, providing free samples, or

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[40] Kelly RJ et al., *Patients and Physicians Can Discuss Costs of Cancer Treatment in the Clinic, J. Oncol. Pract.* 11**,** 4(2015): 308–12.
[41] Hunter WG et al., *What Strategies Do Physicians and Patients Discuss to Reduce Out-of-Pocket Costs? Analysis of Cost-Saving Strategies in 1,755 Outpatient Clinic Visits, Med. Decis. Mak.* 36**,** 7(2016): 900–910.
[42] Hunter WG et al., *Patient-physician discussions about costs: definitions and impact on cost conversation incidence estimates, BMC Health Serv. Res.* 16, 108 (2016).
[43] Shih T, Nasso SF, Zafar SY, *Price Transparency for Whom? In Search of Out-of-Pocket Cost Estimates to Facilitate Cost Communication in Cancer Care, Pharmacoeconomics* 36**,** 108(2018): 259–261.
[44] Surescripts, *Physician Perspectives on Access to Patient Data*, https://surescripts.com/docs/defaultsource/intelligence-in-action/1785_databrief_providersurvey_graphics_final3_web.pdf?sfvrsn=14.
[45] Shih T, Nasso SF, Zafar SY, *Price Transparency for Whom? In Search of Out-of-Pocket Cost Estimates to Facilitate Cost Communication in Cancer Care, Pharmacoeconomics* 36**,** 108(2018): 259–261.
[46] Altomare I et al., *Physician Experience and Attitudes Toward Addressing the Cost of Cancer Care*, *J. Oncol. Pract.* 3(2016): e281-8, 247-8.
[47] Nayak RK & Pearson SD, *The Ethics Of 'Fail First': Guidelines And Practical Scenarios For Step Therapy Coverage Policies, Health Aff.* 33, 10(2014): 1779–1785.

changing or adding supplemental insurance for Medicare patients on traditional plans without prescription drug coverage.[48] Educating providers about these opportunities could help improve the quantity and effectiveness of cost discussions with cancer patients.

We also recommend that the Department take into consideration the medical needs of individual patients when presenting them with information about lower-cost alternatives. Medicare beneficiaries often have medical justifications for the use of a higher cost drug over a potentially lower-cost alternative. In these cases, switching a drug could lead to worse outcomes and/or increased inpatient admissions or emergency department visits.[49]

As the Department continues to explore opportunities to engage cancer patients about the cost of drugs, we encourage pilot testing programs, particularly as there is still much work that needs to be done around the development of accurate cost-estimation tools and provider education.

**Eliminating Cost Sharing for Generics for Lower Income Enrollees**

The President's FY2019 budget proposed eliminating cost-sharing on generic drugs for Medicare beneficiaries who receive the low-income subsidy (LIS). While this proposal was not specifically included in the RFI, we urge the Department to move forward with regulatory changes and work with Congress on the necessary legislative changes to implement this policy.

More than 12 million of the 43 million Medicare beneficiaries with drug coverage under Part D receive assistance with premiums and cost-sharing through the Part D Low-Income Subsidy (LIS) program, known as "Extra Help."[50] To qualify for the program in 2018, beneficiaries must have limited resources and annual income of no more than $18,210 for an individual or $24,690 for a married couple living together.[51]

In general, eliminating LIS beneficiaries' cost-sharing on generic drugs could encourage beneficiaries to utilize these lower cost products. However, since not all cancer therapies have generic equivalents or biosimilars, we would discourage coupling this policy with an increase in cost-sharing for branded products and/or any increase in the use of utilization management tools that hinder LIS beneficiaries' access to branded drugs.

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[48] Hunter WG et al., What Strategies Do Physicians and Patients Discuss to Reduce Out-of-Pocket Costs? Analysis of Cost-Saving Strategies in 1,755 Outpatient Clinic Visits, *Med. Decis. Mak.* 36**,** 7(2016): 900–910.
[49] Nayak RK & Pearson SD, *The Ethics Of 'Fail First': Guidelines And Practical Scenarios For Step Therapy Coverage Policies, Health Aff.* 33, 10(2014): 1779–1785.
[50] CubanskiJ, Damico A, Neuman T, *Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing,* May 17, 2018, https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-onenrollment-premiums-and-cost-sharing/.
[51] Understanding the Extra Help with Your Medicare Prescription Drug Plan, 2018, https://www.ssa.gov/pubs/EN05-10508.pdf.

**Copay Discount Cards**

The RFI raises several questions about manufacturer copay cards, which assist card holders with cost-sharing for a particular drug. Currently, enrollees of Medicare, Medicaid and other federally-funded insurance programs are not able to use these cards because of federal anti-kickback statutes. But for patients who are privately insured or uninsured and need to take an expensive drug, copay cards are often one – or the only – method by which they can afford their treatment. In one 2014 study, researchers found that copay card programs paid for $21.2 million of patients' $35.3 million annual out-of-pocket costs for specialty drugs. In the majority of cases, coupons reduced monthly cost sharing to less than $250.[52]

Specifically, the RFI asks: "Would there be circumstances under which allowing beneficiaries of Federal health care programs to utilize copay discount cards would advance public health benefits such as medication adherence, and outweigh the effects on list price and concerns about program integrity?" As HHS alludes to, and as academic studies have shown, the "failure to take medications as prescribed ['medication nonadherence'] is consistently linked to the exacerbation of chronic conditions, increased health care use, and greater health system costs."[53] Copay cards help patients afford their drug treatments, and thereby improve medication adherence.[54]

Medication adherence is especially important in cancer treatment. Many chemotherapy regimens are timed precisely, and delaying treatment or deviating from prescribed timelines can harm patients.[55,56] Additionally, supportive care drugs (like pain or anti-nausea medication) also must be taken at precise times to alleviate treatment side effects. It is also crucial that some cancer survivors continue with hormone therapy medication after their other treatments. This therapy helps prevent recurrence of their cancer, and it can also represent years of additional costs.

It is very common for cancer patients to have problems affording their medications, and research shows that rising costs for cancer drugs can indeed lead to "cost-related nonadherence" to cancer-related

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[52] Starner CI, et al., *Specialty Drug Coupons Lower Out-Of-Pocket Costs and May Improve Adherence At The Risk Of Increasing Premiums, Health Affairs,* October 2014, https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2014.0497.

[53] Kennedy J & Wood EG, *Medication Costs and Adherence of Treatment Before and After the Affordable Care Act: 1999–2015,* American Journal of Public Health 106, no. 10 October 1, 2016: pp. 1804-1807. https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2016.303269.

[54] Id.

[55] Chavez-Macgregor M, Clarke CA, Lichtensztajn DY, et al., *Delayed Initiation of Adjuvant Chemotherapy Among Patients with Breast Cancer, JAMA Oncology,* March 2016, http://oncology.jamanetwork.com/article.aspx?articleid=2474437.

[56] Darkow T et al., *Treatment Interruptions and Non-Adherence with Imatinib and Associated Healthcare Costs, PharmacoEconomics,* June 2007, Volume 25, Issue 6, pp 481-496, https://link.springer.com/article/10.2165/00019053-200725060-00004.

medication regimens.[57,58,59,60] These problems are more likely to affect women,[61] older African-American and Hispanic cancer survivors.[62] In fact, one study showed that receipt of Medicare Part D low-income subsidies – another way to reduce cost-sharing for some Medicare recipients – "was associated with substantially improved persistence to breast cancer hormonal therapy among white, black, and Hispanic women," and therefore had the potential to also substantially reduce racial and ethnic disparities in survival rates.[63]

While ACS CAN recognizes the Department's concern that manufacturer copay cards encourage patients to use more expensive drugs, we believe the context of cancer treatment is important to consider. Cancer treatment is becoming more personalized and targeted and lower cost generics and biosimilars are not yet available for all cancer drugs. Most doctors treating cancer follow defined, evidence-based treatment protocols based on the type of cancer a patient has, and patient-driven factors (including genetic factors and patient comorbidities). In this context, there is often only one drug that is appropriate to use for a particular cancer patient. If that drug does not have a generic or interchangeable biosimilar equivalent, there are no alternatives for that patient. In this situation a manufacturer copay card cannot influence the choice of drug, because there is no choice available. Copay cards fill a crucial need by enabling cancer patients to afford their life-saving treatment.

ACS CAN strongly encourages HHS to explore ways to help Medicare enrollees afford their drugs, including allowing enrollees to use manufacturer copay cards when a generic or interchangeable biosimilar is not available. We recognize that such a change would likely require revisions to federal statute, and we encourage the Administration to work with Congress to address this issue. In addition, the Administration should consider prohibiting Medicare's supplemental insurers from disallowing beneficiaries from applying any support received from the Office of the Inspector General's favorably reviewed Patient Assistance Programs towards their out-of-pocket obligations.

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[57] Dusetzina SB et al., *Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia, Journal of Clinical Oncology,* February 1, 2014, https://www.ncbi.nlm.nih.gov/pubmed/24366936.
[58] Neugut AI et al., *Association Between Prescription Co-Payment Amount and Compliance with Adjuvant Hormonal Therapy in Women with Early-Stage Breast Cancer, Journal of Clinical Oncology,* http://ascopubs.org/doi/10.1200/JCO.2010.33.3179.
[59] Farias AJ & Du XL, *Association Between Out-Of-Pocket Costs, Race/Ethnicity, and Adjuvant Endocrine Therapy Adherence Among Medicare Patients With Breast Cancer, Journal of Clinical Oncology*, http://ascopubs.org/doi/full/10.1200/JCO.2016.68.2807#.
[60] Lee MM & Khan MM, *Gender differences in cost-related medication non-adherence among cancer survivors, Journal of Cancer Survivorship,* April 2016, Volume 10, Issue 2, pp 384-393, https://link.springer.com/article/10.1007/s11764-015-0484-5.
[61] Lee M & Salloum RG, *Racial and ethnic disparities in cost-related medication non-adherence among cancer survivors, Journal of Cancer Survivorship,* June 2016, Volume 10, Issue 3, pp 534-544, https://link.springer.com/article/10.1007/s11764-015-0499-y.
[62] Biggers A, et al., *Medicare D Subsidies and Racial Disparities in Persistence and Adherence With Hormonal Therapy, Journal of Clinical Oncology*, http://ascopubs.org/doi/full/10.1200/JCO.2016.67.3350.
[63] Id.

**Value-Based Arrangements and Price Reporting**

The RFI posits many questions related to the feasibility of enacting value-based payments for prescription drugs.

ACS CAN supports efforts to promote value in healthcare. When properly utilized, value-based arrangements can improve quality while lowering healthcare costs. However, we note that value-based arrangements may not be appropriate for all categories and classes of drugs. Cancer care can be very specific and only one drug may exist to treat an individual's specific cancer. By better understanding the molecular alterations that cause a given cancer, researchers can develop targeted therapies aimed at specific genetic mutations that drive that cancer.[64] For example, the broad category of tyrosine kinase inhibitors has been developed to treat cancer, but each drug within this category may target a different mutation that is relevant to a small subcategory of patients with a given disease. This targeting means that any comparators within a reference pricing scheme would have to be for the same molecular target, and in many cases, there are only one or two drugs for each target, making reference pricing unsuitable.

Even where there may be multiple therapies for a given type of mutation, (e.g., ALK or EGFR) there are important differences between their performance characteristics, especially when considering first and second-generation drugs from these classes. Any attempts to implement reference pricing on cancer therapeutics must therefore overcome the small category sizes and account for important differences between drugs within a category. As the Department examines the feasibility of indication-based pricing structures, we urge you to balance the impact of the policy with affordability for the patient and advancements in treatments based on personalized medicine, including treatments based on genetic information, and issues related to side-effects and drug-to-drug interactions.

**Indication-Based Payments**

The RFI notes that prescription drugs have varying degrees of effectiveness when used to treat different types of diseases. The RFI seeks comment on whether Medicare or Medicaid should pay the same price for drugs regardless of the diagnosis for which it is used. The RFI also seeks comment on how indication based pricing could support value-based purchasing.

As noted in our comments above, ACS CAN supports efforts to promote value in healthcare. Beneficiaries should be prescribed the drug that is expected to result in the best health outcomes for the beneficiary. This determination can vary depending on the beneficiary's overall health status (e.g., her/his disease or condition, comorbidities, allergies, etc.), as well as non-health factors (e.g., availability of a caregiver, transportation issues to and from treatment, financial considerations, etc.). Such determinations are particularly important in oncology care given that potential side-effects of

[64] While targeted cancer therapies are a relatively new field, more and more promising research is being conducted in this area and new treatments are currently in the pipeline. According to some research up to fifty percent of drugs currently in the clinical pipeline are estimated to involve the use of genetic or molecular markers. American Cancer Society Cancer Action Network, *Fulfilling the Promise of Personalized Medicine for Patients; Background and Overview Paper #1: Patient Expectations and Access Barriers*, July 15, 2015, http://www.acscan.org/content/wp-content/uploads/2014/04/Patient-Expectations-and-Access-Barriers.pdf.

medication can be challenging to manage and few treatment options may exist. Therefore, it is imperative that beneficiaries and their physicians carefully consider and choose the treatment path that best meets the patient's needs.

**Site Neutrality for Physician-Administered Drugs**

The RFI notes that facility fees associated with physician-administered drugs in the Part B and Medicaid programs can vary significantly depending whether the drug is administered in a hospital or hospital owned outpatient departments versus a physician's office.

ACS CAN supports the Department's ongoing efforts to address the payment differential between hospital-owned outpatient departments (HOPD) and physician offices. Studies have shown that drug administration fees are higher for Medicare and for cancer patients in the HOPD setting.[65,66,67] This is compounded by the increase in the number of physician offices that have been acquired by hospitals. Since 2008, there has been a 172 percent increase in the number of private oncology practices acquired by hospitals.[68] As a result, more cancer patients are receiving care in HOPD settings.[69,70] The percentage of Medicare beneficiaries receiving cancer drugs in the HOPD setting rose from 23 percent in 2008 to almost 50 percent in 2016.[71]

As site neutral policies are developed, we urge the Department to ensure that patients' access to treatments is not unduly limited. In some cases, an HOPD setting may be the most medically appropriate for a given patient, particularly if that patient has certain comorbidities or for whom a community setting may not be appropriate. Thus, before the Department enacts major changes, we suggest the use of demonstration projects to better determine whether site neutrality is more appropriate for certain categories and classes of drugs and how the programs can ensure that patients can be ensured that they will continue to have access to the setting of care most appropriate for their needs.

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[65] Wynn BO, Hussey PS, Ruder T, *Policy Options for Addressing Medicare Payment Differentials Across Ambulatory Settings*, RAND Corporation, 2011, https://www.rand.org/pubs/technical_reports/TR979.html.
[66] Fitch K, Pelizzari PM, Pyenson B, *Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data*, Milliman, 2016, http://www.milliman.com/uploadedFiles/insight/2016/trends-in-cancer-care.pdf.
[67] PhRMA, *Cancer Medicines: Value in Context*, 2018, http://phrma-docs.phrma.org/files/dmfile/PhRMA-CancerChart-Pack-2018.PDF.
[68] Community Oncology Alliance, *2016 COA Practice Impact Report*, 2016, https://www.communityoncology.org/2016-coa-practice-impact-report/.
[69] The Moran Company, *Results of Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee- for-Service Beneficiaries,* 2013, http://www.siteneutral.org/wpcontent/uploads/2016/06/16_Final-Moran-Memo.pdf.
[70] Vandervelde A. & Blalock E, *The Oncology Drug Marketplace: Trends in Discounting and Site of Care Executive Summary*, Berkeley Research Group, 2017, https://www.communityoncology.org/wpcontent/uploads/2017/12/BRG_COA-340B-Study_NOT_EMBARGOED.pdf.
[71] Id.

**Site Neutrality Between Inpatient and Outpatient Settings**

The RFI also notes that the Medicare Part A program and Part B program have different reimbursement rates for drugs. Beneficiaries have different cost-sharing depending on whether their drugs are provided under the Part A or Part B program.

As noted in our comments above, we believe that patients should be provided care in the setting that is most appropriate to their needs. With respect to prescription drugs administered in the inpatient versus outpatient setting, the site of care could be dictated by FDA regulations, which may require a drug to be provided in an inpatient setting due to safety concerns. Cancer drugs administered in the inpatient setting are done so due to safety concerns and the decision as to whether these drugs should be administered in the inpatient or outpatient setting requires careful evaluation of many factors, including the specific drug and patient-related factors (e.g., need for prolonged observation, management of adverse side effects).[72] Complications and unplanned emergency room (ER) admissions that may arise could offset any potential savings in the long term. Already, ER utilization and hospital admissions are higher among patients receiving cancer therapies due to complications in managing side effects.[73,74]

In addition to safety issues, we also encourage the Department to consider a cancer patient's direct and ancillary costs when shifting care from the inpatient to outpatient setting. Currently, under Medicare Part A, cancer patients' out-of-pocket costs per episode of care are capped at $1,340 in most cases.[75] Under the Medicare Part B standard benefit design, a beneficiary without supplemental coverage would have to pay an uncapped 20 percent coinsurance. Given the high cost of cancer drugs today, this could leave many Medicare beneficiaries with out-of-pocket costs far-exceeding $1,340. Additionally, if cancer patients must return to the outpatient setting multiple times, they will also incur ancillary costs (e.g., travel, lodging).

**The 340(B) Discount Program**

The original intent of the 340(B) program was to help certain hospitals, clinics and health centers serving a disproportionate number of lower income patients stretch limited dollars by lowering the proportion of their drug spending. With lower costs these entities could provide more charity care – which would include coverage for lower income cancer patients.

Currently, 37 percent of disproportionate share hospitals provide charity care that amounts to less than 1 percent of their total patient costs and almost two-thirds of critical access hospitals provide less

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[72] Foster AE & Reeves DJ, *Inpatient Antineoplastic Medication Administration And Associated Drug Costs: Institution of a Hospital Policy Limiting Inpatient Administration, P T* 42, 6(2017): 388–393.
[73] Lash RS et al., *A Systematic Review of Emergency Department Use Among Cancer Patients, Cancer Nurs.* 40**,** 2(2017): 135–144.
[74] Pittman NM, Hopman WM, Mates M, *Emergency room visits and hospital admission rates after curative chemotherapy for breast cancer, J. Oncol. Pract.* 11**,** 2(2015): 120–5.
[75] Centers for Medicare & Medicaid Services. *Medicare 2018 costs at a glance*, https://www.medicare.gov/yourmedicare-costs/costs-at-a-glance/costs-at-glance.html.

charity care than the national average for short-term, acute care hospitals.[76] This suggests that even though these hospitals have access to lower-priced drugs through the 340(B) program, the savings are not necessarily being invested in charity care as intended. To ensure that the intent of the program is followed as Congress intended, we suggest the Department consider requiring a certain level of charity care (including direct care reimbursement – not just community education programs) in exchange for being eligible to participate in the 340(B) program.

**Global Issues**

The U.S. is a leading innovator in drug development yet consumers in the United States spend roughly three times as much on drugs as their European counterparts and about 3.5 times the price per dose of medicine taken, including generics, compared to their European counterparts.[77] The RFI raises questions about how to address this disparity by making other countries pay drug prices closer to those in the US.

Public access to drugs in many other developed countries occurs in a fundamentally different way than in the United States. In the U.S., a drug must demonstrate to FDA that it is safe and effective before being allowed to enter the marketplace. Once FDA approved, drugs are typically widely available to U.S. consumers. Payment is a mixture of dozens of different private insurance companies, federal programs like Medicare or the Veteran's Administration, and state programs like Medicaid, so there is no single entity that determines national coverage of a drug.

In contrast, many other developed countries have a two-step process for market access. The first step of demonstrating safety and efficacy is the same as in the U.S., but in countries where insurance coverage is nationalized, there is typically a second step that involves a cost-effectiveness evaluation. This evaluation determines whether the added benefit of the drug justifies the proposed cost. This two-step process has several effects. One result is that the process of drug development and marketing can be more complicated by the need to not only prove safety and efficacy, but also to prove cost effectiveness. Often these two separate goals require different clinical studies that add drug development cost and delay time to market.[78] Another result is that drug sponsors will often accept lower prices to satisfy cost-effectiveness thresholds required to be sold in that country. Lastly, this system may result in patients not having access to certain drugs that either have been rejected by the health authority for not meeting cost-effectiveness thresholds or for which the sponsor has decided not to market in a country because of the additional hurdles.

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[76] White House Council of Economic Advisors. *Reforming Biopharmaceutical Pricing at Home and Abroad*. Feb. 2018, https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.
[77] Goldman D, Lakdawalla D, *The global burden of medical innovation*, Brookings, January 30, 2018, https://www.brookings.edu/research/the-global-burden-of-medical-innovation/.
[78] Ciani O, Jommi C, *The Role of Health Technology Assessment Bodies in Shaping Drug Development, Drug Des Devel Ther,* November, 2014, https://www.ncbi.nlm.nih.gov/pubmed/25419117.

As U.S. policymakers look for options to reduce spending on drugs, some have argued that increasing the prices paid by European countries would reduce U.S. spending on prescription drugs and result in greater revenues that would ultimately lead to substantially more innovation worldwide.[79]

As the Department examines global issues around drug prices it should look more closely at the kinds of mechanisms that might be possible through trade arrangements or regulatory standards. The Department will want to keep in mind both short- and long-term implications. For instance, in 2017 nearly 80 percent of the drugs newly approved in the U.S. were approved in the U.S. before being approved in any other country, providing Americans with first access to innovation. Policies that disrupt the existing drug development and approval process may be fruitful in lowering prices, but it will be important to consider additional effects that this disruption may have on how quickly and whether Americans can access innovative therapies relative to the rest of the world. As such, more research on the overall impact of pricing disparities is necessary.

Finally, we must note that the U.S. has a higher population of uninsured individuals relative to other OECD countries, and these individuals incur significantly higher costs relative to individuals in other countries.[80] Thus, one way to reduce the disparity in costs borne by the consumer would be to enact policies to ensure that all consumers in the United States have access to affordable and comprehensive health insurance coverage.

**Access to Reference Product Samples**

The RFI seeks comments on Risk Evaluation and Mitigation Strategies (REMS). REMS are important tools to ensure patients can benefit from potentially beneficial drugs, while limiting risks posed by such drugs if they are used improperly. REMS are often applied to a drug or drug class at the time of approval to ensure an overall positive benefit to risk ratio. REMS-imposed distribution restrictions are meant to ensure that the use of potentially harmful drugs is confined to appropriate uses by restricting custody of REMS drugs only to parties that can ensure that subsequent parties in the custody chain are able to prevent misuse of these drugs. Because the longer a drug is on the market the more we learn about the drug and how it is used, it is wholly appropriate to periodically reevaluate restrictions placed on drugs or drug classes to make sure that patient interests continue to be served.

To foster competition and encourage sample sharing, FDA has already taken steps to certify the adequacy of generic drug developers' safety plans with respect to drug samples subject to REMS programs. FDA has also made it clear that it will allow generic developers to set up parallel REMS monitoring programs if the reference product sponsor is unwilling to share a common system, steps which ACS CAN supports. Thus far, neither of these approaches appear to have increased availability of reference samples for products subject to REMS. Importantly, restricted distribution networks can and do exist outside of REMS requirements, so simply removing FDA-imposed REMS requirements related to

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[79] Goldman D, Lakdawalla D, *The global burden of medical innovation*, Brookings, January 30, 2018, https://www.brookings.edu/research/the-global-burden-of-medical-innovation/.

[80] Sarnak D, Squires D, Kuzmak G, Bishop S, *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?, Issue Brief*, The Commonwealth Fund, Oct. 2017, https://www.commonwealthfund.org/sites/default/files/documents/mediafilespublicationsissuebrief2017octsarnakpayingforrxibv2.pdf.

distribution will not necessarily stop the voluntary use of similarly restricted distribution networks. Therefore, other tools and solutions may be needed to ensure availability of samples.

**Biosimilar Development, Approval, Education, and Access**

ACS CAN supports the creation of the biosimilar drug development pathway to provide additional choice, competition and savings to cancer patients. For biosimilars to flourish, FDA will need to provide clear guidance for developers of biosimilars, and providers and patients will need education to instill confidence in the rigorous review of safety, quality and efficacy of biosimilars. Patients and providers are two distinct populations with different educational needs and materials should be developed accordingly.

Different stakeholders also look to different authorities to provide such education. For example, some may look to government sources for education, while others seek out information from patient advocacy groups, providers, or pharmaceutical companies. It is therefore important that educational materials be developed by multiple sources beyond just the government. Accordingly, ACS CAN has produced a suite of biosimilar educational materials aimed at patients.[81] FDA has already produced high quality educational materials targeted toward physicians, which have been helpful. We would recommend that they additionally create patient-focused materials using language and concepts tailored toward the lay public. Patients also need to understand the distinctive role of interchangeable biosimilars under the Biologics Price Competition and Innovation Act and any particular treatment under Medicare.

Beyond federal activities, individual state policies play a key role in biosimilar uptake. State pharmacy acts govern the use of interchangeable biosimilars, and the content of these laws will enable or impede adoption of biosimilars. ACS CAN has been active in ensuring that these laws are updated in all 50 states and the District of Columbia to ensure that patients have appropriate access to these lower cost options while maintaining the doctor-patient relationship.

Currently there are no interchangeable biosimilars, but FDA should finalize guidance on required evidence to demonstrate interchangeable status. Within cancer, most biologics are not picked up by a patient at a pharmacy, but rather are prescribed and intravenously administered within a doctor's office. Therefore, it is unclear what role interchangeability will have on prescribing within oncology.

[81] For more information visit www.acscan.org/biosimilars.

**Conclusion**

ACS CAN appreciates the opportunity to respond to the RFI. We look forward to working with the Department on ways to encourage innovation of new and affordable cancer medications, and would welcome the opportunity to meet with you to discuss our comments in more detail. Please feel free to contact me directly or have your staff contact Kirsten Sloan, Vice President – Policy at Kirsten.Sloan@cancer.org or Keysha-Brooks-Coley, Vice President – Federal Advocacy & Strategic Alliances at Keysha.Brooks-Coley@cancer.org if you have any questions.

Sincerely,

Christopher W. Hansen
President
American Cancer Society Cancer Action Network