The leading education and advocacy organization for the multidisciplinary cancer team

Association of Community Cancer Centers

July 16, 2018

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

BY ELECTRONIC DELIVERY

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs Request for Information (RFI).[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 24,000 cancer care professionals from approximately 1,100 hospitals and more than 1,000 private practices nationwide. These include cancer program members, individual members, and members from 34 state oncology societies. It is estimated that 65 percent of cancer patients nationwide are treated by a member of ACCC.

The cancer care delivery infrastructure is a fragile construct of hospital outpatient departments and physician offices working together to provide care to patients in their communities. Physicians and providers face growing numbers of patients requiring cancer care, and their ability to provide appropriate care depends on several factors, including adequate Medicare payment rates for oncology services, including chemotherapy drugs, radiation oncology, and other important services. ACCC is committed to preserving and protecting the entire continuum of quality cancer care for our patients and our communities, including access to appropriate cancer therapies in the most appropriate setting.

The health care payment and delivery paradigm in the United States is increasingly shifting to a value-based system, and community cancer centers are part of this reform effort. We fully support the overarching goal of this shift to bend the cost curve by improving care, providing the right care at the right time, reducing over-treatment and under-treatment, and reducing hospital admissions and readmissions. ACCC programs have a long history of working with CMS on meaningful payment

[1] 83 Fed. Reg. 22,692 (May 16, 2018).

reform, including most recently partnering with CMMI to achieve a shared goal of improving care and reducing costs for cancer patients through the Oncology Care Model (OCM). We also recognize the need for a broad, national conversation about pharmaceutical pricing and to identifying solutions for reining in drug costs for the Medicare program and its beneficiaries. However, we also believe this conversation needs to consider the costs and benefits of all aspects of cancer care. HHS' Blueprint is too narrowly focused on drug costs, without considering the full array of items and services needed to treat cancer patients.

Further, any policy solution to rein in drug costs must preserve patients' access to – and ability to afford – quality cancer care and, relatedly, mitigate any impact on already reduced payment rates for cancer providers. As we discuss in more detail below, many of our members are already challenged to provide care in their communities due to reduced payment rates because of sequestration, decreasing drug administration rates, and under- or unreimbursed services required to provide quality cancer care. Additionally, ACCC's members strive to provide the best care possible to their patients, including the most appropriate drug therapies, with the choice of treatment being guided by clinical evidence and the patient's needs, regardless of cost. While it is our responsibility to ensure appropriate utilization and to provide the right drug to the patient at the right time, ACCC physicians and providers have no control over drug prices. Any policy approach to lower drug costs should not hold patients or providers accountable for a problem they did not create.

Our comments, in brief, are as follows:

- If HHS moves forward with a voluntary alternative to acquiring Part B drugs through the Medicare program, such as an updated Competitive Acquisition Program (CAP), it must adopt sufficient modifications to the program to preserve patient access to drugs, maintain provider flexibility, and permit providers to choose whether they wish to participate in the program based on whether it will help them best serve their patients' needs, and not in response to punitive reimbursement cuts.
- HHS should not impose Medicare Part D utilization management requirements on Medicare Part B drugs or move these drugs to Medicare Part D as doing so would reduce patient access and could increase costs to the Medicare program and patients. In addition, HHS should clarify how these changes would work in practice.
- HHS should ensure that payment rates reflect the true costs of providing care at a particular site of service.
- HHS should ensure that any proposals related to modifying the 340B Drug Pricing Program encourage all oncology providers to treat underserved patient populations.

We address these issues in more detail further below.

I. The CAP

The RFI asks for comment on the changes that "vendors and providers [would] need to see relative to the 2007-2008 implementation of [the CAP] in order to successfully participate in the program."[2] The RFI also asks whether "there [are] a sufficient number of providers interested in having a vendor selected through a competitive bidding process obtain these drugs on their behalf, and bear the financial risk and carrying costs."[3]

[2] *Id.* at 22,697.
[3] *Id.*

ACCC is concerned about resurrecting the CAP program because of the significant challenges in providing drugs to patients under the prior version of the program, as well as concerns about whether reimbursement for drug administration and other services will be sufficient to cover the full costs of treating patients. As originally implemented, the CAP program often resulted in delays in patient access to medications and inhibited provider flexibility in adopting patient treatment regimens. These issues would be difficult to overcome in any updated version of the CAP, particularly with respect to cancer drugs.

However, we also understand that some practices may desire an alternative to the current model for acquiring Part B drugs through the Medicare program that is voluntary, appropriately structured to protect patients, and that will reimburse them for the true cost of providing quality cancer care. Should HHS choose to move forward with a modified CAP, ACCC urges HHS to take steps to address these issues to ensure timely patient access to necessary medications and maintain provider flexibility. ACCC also urges HHS not to make any updated version of the CAP mandatory or to take steps to incentivize provider participation that would effectively make the CAP mandatory, such as reducing reimbursement for drugs under the existing average sales price (ASP) reimbursement system.

A. Few providers are likely to participate in an updated CAP

Few provider practices were interested in consistently participating in the first version of the CAP, and we expect that few physicians will want to participate in an updated version of the program. The CAP experienced a high rate of turnover of physician participants from year to year, likely as physicians discovered that the CAP did not work for them.[4] This lack of participation is unlikely to change if HHS were to adopt an updated CAP for a number of reasons.

First, any version of the CAP that requires physicians to obtain each dose of a drug for a specific patient would impose administrative burdens that could have a negative impact on a provider's ability to provide the best patient care and ensure that patients are getting the drugs they truly need.

Second, providers are unlikely to want to participate in the CAP if they are not assured that reimbursement for the other items and services they provide will be sufficient to cover the costs of providing quality care. Currently, reimbursement for drugs helps practices provide critical patient support services and pharmacy services that are essential to providing the drug and quality patient care but are not adequately reimbursed as separate services. Relevant social services include assistance with navigating the process of financing cancer care services, including communicating with insurers, social services, transportation services, dietary guidance, and chaplain support, all of which are unreimbursed and yet fundamental to providing patients with support during their illness. Pharmacy service costs for cancer treatment providers include the costs of furnishing clean rooms, maintaining supplies, solutions, hoods, and storage, and other administrative costs associated with managing chemotherapy inventory and preparing drugs for administration. Practices would incur many of these costs even if they were no longer responsible for purchasing the drugs themselves. These services are only going to become more essential as cancer treatments become more complex.

Moreover, should HHS adopt an updated CAP, providers likely would face additional administrative costs and could need to hire at least one additional full-time equivalent (FTE) employee to manage drug inventory purchased through the CAP and ensure it gets to the right patient. Practices would

[4] RTI International, Evaluation of the Competitive Acquisition Program for Part B Drugs, at 59 (2010) [hereinafter Evaluation of the Competitive Acquisition Program for Part B Drugs], *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf.

have to hire an additional FTE, instead of using an existing one, because they would continue to purchase drugs not covered under the CAP demonstration, including drugs for their non-Medicare patients, through the regular reimbursement and distribution system.

In addition, practices are already facing financial restraints due to sequestration's reduction in reimbursement for drugs and services. Further reducing practices' revenue under an updated CAP would leave providers with even less to cover patient support services and pharmacy services, as well as the additional administrative costs incurred under the CAP. If HHS chooses to move forward with an updated CAP, it should ensure that it adopts a mechanism to ensure that providers will be appropriately compensated for all of the services they provide. For example, HHS could consider adopting a new inventory management fee under the CAP to cover the costs of these services, similar to the Monthly Enhanced Oncology Services payment available under the Oncology Care Model.[5]

B. It will be difficult to overcome the distribution and access issues of the original version of the CAP program

The original version of the CAP faced significant challenges that will be difficult to overcome when implementing an updated version. For example, the laws governing the CAP and requirements imposed by vendors often delayed the delivery of a CAP covered drug to providers and consequently to patients because:

- Physicians had to submit a prescription to a CAP vendor before the vendor could deliver the drug to the physician.[6]
- Physicians could not transfer drugs across multiple practice locations except pursuant to their agreement with the CAP vendor.[7] In ACCC's experience, these agreements led to restrictions on the ability of physicians to transfer these drugs to the practice's location that was most convenient for the beneficiary. Physicians therefore had limited ability to work around the delays imposed by needing to order each dose of a drug for a specific patient and location from the CAP vendor.

This lack of flexibility guarantees that a provider will face difficulties in tailoring treatment regimens to specific patients under the CAP. For example, if a patient has an adverse reaction to a particular medication and needs to quickly switch prescriptions, her physician would face additional administrative burdens having to obtain or restock the drug the patient needs under the CAP, compared to using a drug out of the physician's own supply and billing for it. In addition, any drugs the physician ordered from the CAP vendor but could not administer are at risk of being discarded if the physician and the vendor cannot process a new prescription to use the drug for another patient. This process imposes cost burdens on the physician and the vendor as they seek to avoid wasting drugs.

In practice, this lack of flexibility in the delivery of drugs was particularly problematic for cancer patients. After HHS postponed implementation of the CAP effective December 31, 2008, it hired RTI International to perform an analysis of the program to determine its successes and failures.[8] This evaluation found that physicians particularly relied on certain emergency measures in the CAP to timely dispense the appropriate dosage form and strength of a drug to patients. These measures included the

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[5] The Centers for Medicare & Medicaid Services (CMS), Oncology Care Model: OCM Performance-Based Payment Methodology Version 3.2 at 7 (Dec. 27, 2017).
[6] Social Security Act (SSA) § 1847B(b)(4)(E).
[7] 42 C.F.R. § 414.908(a)(3)(xii).
[8] Evaluation of the Competitive Acquisition Program for Part B Drugs at 9.

emergency restocking provision[9] and "the furnish as written" provision.[10] The former permitted physicians to use a drug in their own inventory and then immediately resupply it with a drug purchased through the CAP in situations where the drugs were immediately necessary, the physician could not have predicted she would need the drug, the vendor could not supply it fast enough, and the situation qualified as an emergency.[11] Under the latter, a physician could purchase a drug through the ASP reimbursement system if a dosage form or strength of a drug was not available through the CAP.[12]

Under the CAP, physicians used the emergency restocking provisions for breast, prostate, colorectal, and other cancers and tumors 16 percent of the time in 2006 and 21.7 percent of the time in 2007.[13] In 2006 and 2007, they used the emergency restocking provisions for chemotherapy 26.5 and 25.5 percent of the time respectively.[14] Finally, they used the emergency restocking provisions for lung, upper digestive tract, and other severe cancers 28.1 and 27.8 percent of the time in 2006 and 2007 respectively.[15]

In addition, under the CAP in 2006 and 2007, physicians used the "furnish as written" provision for breast, prostate, colorectal, and other cancers and tumors 3.9 and 5.4 percent of the time respectively.[16] They used the "furnish as written" provision for chemotherapy 5.4 and 8.9 percent of the time respectively.[17] They used the "furnish as written" provision for lung, upper digestive tract, and other severe cancers 3.5 and 3.6 percent of the time respectively.[18] These categories of codes were among the top twenty that most used the emergency restocking and "furnish as written" provisions.[19]

Based on this data, it seems clear that the only way for physicians to make the CAP work when treating cancer patients was to circumvent the CAP's standard procedures and rely on the emergency restocking and "furnish as written" provisions, likely to accommodate changes in patient scheduling or changes in a planned course of treatment. These obstacles are so fundamental to the nature of the CAP that they may be difficult to overcome in an updated CAP.

C. If HHS moves forward with an updated version of the CAP, it must take steps to protect patient access and preserve provider flexibility

Should HHS choose to move forward with an updated CAP program, HHS should consider either excluding cancer drugs from this program, as the above data suggests that they clearly are not suited for it, or HHS must develop a means of streamlining the CAP distribution system to avoid the above issues. As part of any streamlined CAP system, HHS must maintain and improve the emergency restocking and "furnish as written" provisions to make drugs available to patients when needed, accommodate changes that frequently need to be made at a moment's notice in response to a patient's evolving health and comorbidities, and preserve provider and patient choice with respect to their prescriptions. These changes

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[9] 42 C.F.R. §§ 414.902, 414.906(e).
[10] *Id.* § 414.908(a)(3)(xiv).
[11] *Id.* § 414.906(e). An emergency situation is defined as "an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of" the rule are met. *Id.* § 414.902.
[12] *Id.* § 414.908(a)(3)(xiv).
[13] Evaluation of the Competitive Acquisition Program for Part B Drugs at 53.
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*

should also include a mechanism for physicians to disenroll from the updated CAP mid year if it turns out that the system is not working for their patients, instead of requiring physicians to enroll for a whole year.[20] Finally, to further maintain patient and provider access to the drug of their choice, CAP vendors should not be permitted to adopt closed formularies under which a vendor might actually get to exclude or threaten to exclude a drug from coverage and should not be permitted to adopt utilization management tools, such as prior authorization requirements and step therapy, as suggested by MedPAC for its proposed drug value program (DVP).[21] As discussed further below, these measures might reduce or delay patients' access to drugs that they truly need.

D. Providers should not be forced to participate in any updated CAP by HHS adopting punitive measures to force provider participation

ACCC also urges HHS not to make any updated CAP mandatory or to take any measures that would effectively make the CAP mandatory by forcing providers to choose the CAP or risk financial ruin. The Medicare Payment Advisory Commission (MedPAC) recently proposed a drug value program (DVP), which could be viewed as a potential framework for a modified version of the CAP.[22] As proposed by MedPAC, the DVP would incentivize provider participation in the CAP by gradually phasing out the 6 percent payment given to providers in addition to ASP under the traditional reimbursement system.[23] In practice, reducing the additional 6 percent payment to ASP would only serve to penalize providers choosing not to participate in the CAP and not encourage improvements in care. Without adequate reimbursement for the full array of services needed to provide quality care under either the standard reimbursement system or an updated CAP, providers would be caught between two bad choices, neither of which would be sustainable nor would result in better care for patients. For these reasons, ACCC urges HHS not to use punitive measures under the current ASP system as a tool to force provider participation in an updated CAP.

II. Subjecting Drugs Currently Covered Under Medicare Part B to Part D Utilization Management Requirements

The RFI asks for feedback on the request in the President's budget for CY 2019 for authority to move some drugs currently covered under Medicare Part B to Medicare Part D, in particular with respect to which drugs should be moved from Part B to D and how to reduce out-of-pocket costs for these drugs for the 27 percent of beneficiaries that do not have prescription drug coverage under Part D.[24] It is our understanding that, instead of actually moving drugs currently covered under Part B to Part D, HHS also may be considering adopting Part D utilization management tools and Part C formulary requirements. No matter how HHS decides to implement this suggested change, ACCC has serious concerns about its impact on Medicare beneficiaries because it risks increasing patient out-of-pocket costs and reducing patient access. This proposal will also likely increase costs for Medicare by reducing medication adherence and, generally, it is unclear how it could be operationalized in practice. These comments are addressed further below.

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[20] 42 C.F.R. § 414.906(a).
[21] MedPAC, Report to the Congress: Medicare and the Health Care Delivery System at 32 (June 2017) [hereinafter MedPAC Report], *available at* http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0.
[22] MedPAC Report at 32.
[23] *Id*. at 58.
[24] 83 Fed. Reg. at 22,697.

A. ACCC urges HHS not to subject drugs currently covered under Medicare Part B to a system of tiered copayments, prior authorization, step therapy, or quantity limits that applies under Part D

If HHS were to move drugs currently covered under Part B to Part D or if the agency were to adopt Part D utilization management tools and Part C negotiation tools, these changes could severely limit patient access to the drug that works best for them. These tools could include:

- *Subjecting drugs currently covered under Medicare Part B to a system of tiered copayments*. Medicare Part D plans are currently permitted to adopt a system of tiered copayments for drugs such that the plan's preferred drugs may be covered at lower cost sharing amounts compared to nonpreferred drugs.[25] Medicare Part C plans are also permitted to adopt a system of tiered copayments for most items and services, but must ensure that the overall cost sharing amounts remain actuarially equivalent to the cost sharing under Medicare Parts A and B.[26] Certain categories of items and services under Medicare Part C, such as chemotherapy administration, may also be subject to tiered copayments so long as those copayments do not exceed the copayment amounts permitted under Medicare Parts A and B.[27] Adopting tiered copayments would mean that patient access to different drugs will depend on affordability and, in some cases, the drug that a provider determines may be best for the patient may be financially beyond the patient's reach. Part D plans are also required to adopt an exceptions process to these tired copayment requirements, but this process is not available for drugs covered under specialty tiers;[28] it still means the decision of which drug should be covered rests in part in the hands of the payor, not the patient and provider; and, even if a patient and provider's choice of drug is ultimately covered, this system delays patient access to drugs.
- *Subjecting drugs currently covered under Medicare Part B to prior authorization and step therapy requirements and quantity limits.* Part D plans are permitted to use prior authorization and step therapy requirements and impose quantity limits on prescription drug coverage.[29] Prior authorization requirements obligate patients to first seek approval from the payor before receiving coverage for a drug. Step therapy requirements require patients to first try the medication that may not, in a prescriber's determination, be best for them before the patient's choice of medication is covered. Quantity limits serve as a payor-imposed cap on the amount of a prescription that can be dispensed to a patient at a given time. Under Medicare Part C, imposing tools such as step therapy on Medicare Part B items or services is only permitted to the extent it is permitted under original Medicare.[30]

These tools limit patient access to the medication of their choice by requiring patients to shoulder increased cost sharing or navigate additional administrative burdens before they may access their drug of choice. They also risk substituting the payor's judgment of what medication may be best for a particular patient for that of the prescribing practitioner. A prescriber may make this determination after consideration of the progression a particular patient's disease, the possible side effects from the drug, and the patient's comorbidities. In addition, these tools may limit prescriber flexibility to tailor a patient's

[25] 42 C.F.R. § 423.104(d)(2)(ii).
[26] SSA § 1852(a)(1)(B); Medicare Managed Care Manual (MMCM), ch. 4, § 10.2.
[27] SSA § 1852(a)(1)(B); 42 C.F.R. § 422.100(j); MMCM, ch. 4, § 50.1.
[28] 42 C.F.R. § 423.578(a).
[29] *Id*.. § 423.120(b)(1)(x).
[30] CMS, Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services (Sept. 17, 2012).

treatment regimen as they see fit. For all of these reasons, ACCC urges HHS not to impose these tools on drugs currently covered under Medicare Part B.

B. ACCC urges HHS not to subject drugs currently covered under Medicare Part B to Part D utilization management requirements as doing so could increase costs to the Medicare program

Subjecting drugs currently covered under Medicare Part B to Part D utilization management requirements and Part C negotiation tools could increase costs to the Medicare program. While the goal of this suggested change seems to be lowering Medicare spending on drugs, if the unintended consequence of these changes is that patients have reduced access to drugs because of the adoption of utilization and negotiation tools, then patient adherence to their medication regimens could decrease. This decrease could in turn lead to poorer management of health conditions, putting patient health and safety at risk, and more visits to physicians' offices and hospitals thereby driving up costs in other parts of the Medicare system and increasing Medicare spending overall. ACCC therefore urges HHS to consider the impact of subjecting drugs covered under Medicare Part B to Part D utilization management and Part C negotiation tools comprehensively to ensure that what may appear to be savings in one part of the program does not lead to increased costs in another.

C. ACCC urges HHS not to move drugs currently covered under Medicare Part B to Part D as doing so will price many patients out of being able to access necessary medications

Should HHS literally move drugs currently covered under Medicare Part B to Part D, this could dramatically increase the cost-sharing for these drugs for patients with Medicare Part D coverage, due to the Part D cost sharing requirements. These requirements include a deductible of $405, up to 25 percent cost sharing up to the initial coverage limit of $3,750, up to 35 percent cost sharing after that until the patient reaches the out-of-pocket threshold of $5,000, and up to 5 percent cost sharing in the catastrophic phase.[31] These high out-of-pocket costs for Medicare Part D beneficiaries meant that in 2015 the 1 million Medicare Part D beneficiaries who had spending above the catastrophic threshold and did not have low-income subsidies spent an more than $3,000, on average, out-of-pocket.[32] In addition, ten percent of Medicare Part B beneficiaries with cancer spent more than $6,000 in 2015.[33] And these numbers do not include other out-of-pocket spending incurred by these beneficiaries for their other medical care.

In addition, much of a patient's out-of-pocket expenses under Medicare Part D tends to occur early in the year,[34] such that patients may have to shoulder the brunt of their out of pocket costs in the first few months until they reach the out-of-pocket threshold, instead of getting to spread these costs out over the full twelve months. Many patients may feel they can no longer afford their medications long before they reach that threshold and may begin to pick and choose which prescriptions they actually fill and take, creating medication adherence and ultimately patient health and safety issues. In addition, the varying nature of these cost-sharing amounts may make it difficult for beneficiaries to predict what their out-of-

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[31] SSA § 1860D-2(b); 42 C.F.R. § 423.104(d); CMS, CY 2018 Call Letter at 48, 54 (Apr. 3, 2017), *available at* https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf.

[32] Juliette Kubanski, et al., No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending, Kaiser Family Foundation, (Nov. 7, 2017), *available at* https://www.kff.org/medicare/issue-brief/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending/.

[33] *Id*.

[34] *See generally* Jalpa A. Doshi, PhD, et al., *Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon,"* 23 Am. J. Managed Care S39 (2017).

pocket contribution may be at any given point during the year, making it difficult to plan in advance for these costs.

Finally, moving drugs from Medicare Part B to Part D would be even more problematic for the 27 percent of Medicare beneficiaries without Part D drug coverage.[35] The Kaiser Family Foundation estimates that 17 million of 59 million Medicare beneficiaries in 2017 did not carry a Medicare Part D policy.[36] These beneficiaries may be forced to shoulder the burden of purchasing Medicare Part B drugs moved to Part D entirely on their own or spending even greater out-of-pocket costs.

For these reasons, ACCC urges HHS not to move any drugs currently covered under Medicare Part B to Part D, and in particular not to move drugs used to treat cancer from Part B to Part D given the particularly high out-of-pocket costs that cancer patients face.

D. ACCC urges HHS to provide much needed clarification of what subjecting drugs currently covered under Medicare Part B to Part D would look like

As the suggestion to subject drugs currently covered under Medicare Part B to Part D currently stands, it is unclear what HHS is intending to do with these drugs in practice. Without this detail, it is difficult to provide HHS with detailed feedback on the implications of this change for Medicare beneficiaries. While we know that subjecting Part B drugs to Part D requirements, as described above, would reduce patient access and could increase patient out-of-pocket costs, ACCC also urges HHS to provide much needed clarification of how it would operationalize this proposal. Areas for clarification could include:

- How these drugs would be distributed, through the Medicare Part B physician-administered drug distribution system or the Part D distribution system.
- If these drugs were moved to Medicare Part D, how patients would access any necessary drug administration services, and whether they would be expected to "white bag," *i.e.*, have their physician acquire a drug from the pharmacy for administration, or "brown bag," *i.e.*, acquire the drug from the pharmacy themselves and bring it the physician for administration, their drugs. If patients would be expected to white or brown bag their drugs, HHS should explain how it would ensure that these additional steps in the distribution and drug administration system would not delay patient access to the drugs or compromise the safety of medications subject to specific storage and handling requirements.
- How HHS would address provider billing for these drugs. Currently, there is no mechanism for providers to bill Part B for their drug administration services[37] while separately billing Part D for drugs, and there is no mechanism for Part D to cover physician administration services.[38]

Clearly, any movement of drugs from Part B to Part D would require extensive notice and opportunity for comment before it could be implemented. ACCC urges HHS to provide much needed clarification of how this change would work and solicit additional feedback so that stakeholders may comment on the implications of these operational concerns in practice.

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[35] 83 Fed. Reg. at 22,697.
[36] The Medicare Part D Prescription Drug Benefit, Kaiser Family Foundation (Oct. 2, 2017), *available at* https://www.kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/.
[37] *See* SSA §§ 1832(a)(2)(B), 1861(s)(2)(A) (stating that medical and other health services covered under Medicare Part B include drugs and biologicals furnished incident to a physician's professional service but not addressing a means for coverage of drugs under Medicare Part D and drug administration services under Part B to be covered together).
[38] *See* SSA § 1860D-2 (providing for drug coverage under Part D without mention of administration services).

III. HHS Should Only Adopt Payment Rates That Truly Reflect the Costs of Care Provided at a Particular Site of Service

The RFI asks for feedback on site neutral payments for physician administered drugs across the inpatient and outpatient settings and hospital outpatient departments and physician offices.[39] In general, ACCC supports payment rates that reflect the unique costs of providing care in a particular setting and are based on data that is specific to that setting and the costs that are incurred. What this means in practice is that payments for a particular item or service may be different when it is provided in a hospital inpatient setting, and outpatient department, or a physician office if there are significant differences in the way services are provided in each of those settings. For example, hospitals may bear additional costs due to being open longer hours and tending to treat more complex and sicker patients.[40] Advanced cancer treatments, for example, often are associated with considerable risk and many are available only in the hospital setting. These additional service capabilities come at an increased cost and hospitals should be compensated for them.

In addition, hospital payment rates under the outpatient prospective payment system (OPPS) are calculated based on different data and methodologies than payment rates under the physician fee schedule (PFS) making these rates not directly comparable. For example, payment rates under the OPPS often include the costs of packaged items and services while services under the PFS are calculated for individual services. Site neutral payments would be inappropriate if they do not consider the differences in these two reimbursement systems and instead blindly assume that a payment that can work for one setting can work for the other.

Despite the differences in costs across sites of care and differences in reimbursement methodology, HHS nevertheless sometimes equates the two systems when determining payment rates in practice. Under Section 1833(t)(1)(B)(v) and (t)(21) of the Social Security Act, Congress directed HHS to adopt a payment system for certain items and services provided in off-campus outpatient departments outside of the OPPS (nonexcepted off-campus departments).[41] Though the payment rates under the OPPS are fundamentally distinct from rates under the PFS, HHS chose to determine reimbursement for these items after comparing the payment for the top 25 most billed codes in off-campus provider based departments under the PFS to the OPPS.[42] For CY 2018, HHS ultimately adopted an adjustment in the payment rate for these services of 40 percent of the rate for the same services under the OPPS.[43] This comparison overlooked significant differences in how the rates were calculated, including differences in packaging policies and definitions of clinic visits. Any future consideration of site neutral payments must avoid this mistake and determine payment rates based on apples-to-apples comparisons of services and rate setting methodologies to ensure that payment rates reflect the costs of providing care at a particular site of service.

IV. HHS Should Ensure That Any Proposals Related to Modifying the 340B Drug Pricing Program Encourage All Oncology Providers to Treat Underserved Patient Populations

The RFI also asks for feedback on the 340B Drug Pricing Program, and it asks whether changes could be made to "help refocus the program towards its intended purpose."[44] ACCC believes that as HHS considers reforms to the 340B Program, the agency should work with Congress and the Health Resources

[39] 83 Fed. Reg. at 22,697.
[40] 82 Fed. Reg. 52,976, 53,019 (Nov. 15, 2017).
[41] SSA § 1833(t)(1)(B)(v), (t)(21).
[42] 82 Fed. Reg. at 53,021.
[43] *Id*. at 53,027.
[44] 83 Fed. Reg. at 22,699.

and Services Administration (HRSA) to support policies that encourage and, at a minimum, do not discourage, medical oncology providers from treating underserved populations, including low-income Medicare beneficiaries, Medicare-only, Medicaid, uninsured and dual-eligible cancer patients. ACCC members provide cancer care in private practices and hospitals, both academic and community-based, and for-profit and not-for-profit. The diversity of our membership and vantage point of all care settings for cancer care uniquely positions ACCC to comment on the broader reforms needed to sustain the 340B program.

Historically, the 340B program has served a critical role in the delivery of cancer care. Today, the 340B program helps some of our members provide comprehensive cancer services to high numbers of low-income Medicare beneficiaries, Medicare-only, Medicaid, uninsured and dual-eligible cancer patients. In most cases, our members reinvest the 340B savings they realize from the discounted pricing into the provision of a full array of services that result in high quality cancer care for these beneficiaries, including social services, nutrition counseling, and psychosocial support. Most of these services are not separately payable, and many of our members participating in the program have said that they could not continue to provide these services without the savings from the 340B program.

At the same time, other members have raised concerns that the 340B program is no longer serving the populations it originally intended. Instead, these members have pointed out that some hospitals eligible for the 340B program have expanded the program to include areas that are not underserved, causing market and delivery distortions. Moreover, many of these members, both physician offices and non-participating cancer programs, indicate they also treat underserved cancer patients, yet do not have access to the program.

Recent proposals from HHS on the 340B Program have been flawed because they have focused on payment rates to eligible providers rather than who should be eligible for this program. ACCC wants a 340B program that supports and encourages all providers – both physician offices and hospital-based cancer programs – to serve low-income Medicare beneficiaries, Medicare-only, Medicaid, uninsured, and dual-eligible cancer patients. HHS should use its resources to identify which patients eligible providers serve and where underserved Medicare beneficiaries reside. This would allow organizations like ACCC and others to direct our resources in those areas. In the meantime, ACCC has developed a set of principles for 340B sustainability and reform that includes specific steps that can be taken to modify and strengthen the program.[45]

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We appreciate the opportunity to comment on the Blueprint RFI. If you have any questions about these comments, please do not hesitate to contact Leah Ralph, ACCC Director of Health Policy at lralph@accc-cancer.org or (301) 984-9496 ext. 223.

Respectfully,

Thomas A. Gallo, MS, MDA
President, Association of Community Cancer Centers

[45] ACCC Principles for 340B Drug Pricing Program Sustainability and Reform. September 2017. https://www.accc-cancer.org/docs/Documents/advocacy/pdf/2017-accc-340b-principles