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May 9, 2016

The Honorable Sylvia Burwell
Secretary
Department of Health and Human Services
Attention: CMS-1670-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1670-P – Medicare Program; Part B Drug Payment Model; Proposed Rule
81 Fed. Reg. 13230 (March 11, 2016)

Dear Secretary Burwell:

The American Cancer Society Cancer Action Network (ACS CAN), appreciates the opportunity to comment on the Medicare Part B Drug Payment Model proposed rule. 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.

In 2016, nearly 1.7 million new cases of cancer will be diagnosed in the United States.[1] Because the incidence of cancer increases with age – 86 percent of cancers in the U.S. are diagnosed in people 50 years of age or older[2] – cancer and the therapies used to fight the disease have an enormous impact on the Medicare program. Cancer patients and survivors rely on drug therapies for life-saving treatments; thus, it is paramount that any new payment model must ensure that beneficiaries have access to medically necessary treatments in the setting that is best for them.

ACS CAN is deeply troubled by the proposed Part B Drug Payment Model in its current form. We are concerned that, as currently proposed, the demonstration does not protect cancer patients' access to the life-saving drugs needed to treat their disease. We are also concerned that system capacity needed by cancer patients may be negatively impacted as well.

We are particularly concerned that the project's breadth and scope goes well beyond the standard size of a demonstration project and could directly impact a cancer patient's access to care. Cancer patients already face access problems. The number of small oncology practices has declined – from 64 percent in 2014 to 41 percent in 2015[3] – and this provider consolidation makes it harder for beneficiaries to access

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[1] American Cancer Society. Cancer Facts & Figures: 2016. Atlanta: American Cancer Society, 2016, available at http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/.

[2] Id.

[3] American Society of Clinical Oncology, State of Cancer Care in America, available at http://www.asco.org/sites/new-www.asco.org/files/content-files/research-and-progress/documents/2016-socca-report.PDF.

cancer care, particularly in rural areas where only 5.6 percent of oncologists provide service.[4] We are worried that the demonstration, as designed, could result in more oncologists leaving their practices, further exacerbating beneficiary access to needed cancer care. The stated goal of the demonstration project is to improve patient quality and lower spending but, as outlined in the proposed rule, the Part B Drug Payment Model could actually result in cancer patients getting care in higher-cost, less desirable settings like hospital outpatient departments. For these reasons we strongly urge CMS to reconsider implementing the Part B Drug Payment Model on a national scope. We also strongly suggest CMS outline how it intends to monitor in real time the effect of any new model on cancer patients' access to the medications and what safeguards it will put in place to ensure that if cancer patients' access is compromised immediate steps can take place to address any access problems.

Beyond these major issues we also have other concerns and questions highlighted below including:

- *Timing*: ACS CAN is extremely concerned that the implementation timeline is unrealistic given the magnitude and scope of the proposed Part B Drug Payment Model. Effective education and outreach about the Part B Drug Payment Model cannot begin until the model has been re-scoped into a viable final form and we do not believe the proposed timeframe provides adequate time to effectively educate beneficiaries, physicians, and suppliers about the proposed changes. As discussed in more detail below, ACS CAN has serious concerns with some of the proposed policies contained in the Part B Drug Payment Model and we urge CMS to address these concerns before it even considers implementing any new payment model.
- *Impact on Cancer Care*: The budget neutrality of Phase I will result in significant reductions in reimbursement to oncologists for some cancer drugs. According to one analysis, more than 50 percent of the payment reductions are expected to come from 10 drugs, seven of which are used to treat cancer.[5] We are concerned that this proposal, absent changes, has the potential to result in beneficiaries being unable to access their cancer medications in their preferred setting of care. The payment reductions combined with the Value Based Purchasing Tools in Phase II will accentuate this concern about beneficiaries obtaining necessary care. CMS must establish specific beneficiary protections and evaluation measures as discussed in more detail in our comments below.
- *Shifting to Higher Cost Settings of Care*: One unintended consequence of the Part B Drug Payment Model will likely be a shift in some care to higher-cost settings. Unfortunately, if providers are unable or unwilling to dispense a medically necessary Part B drug due to the reimbursement rate, beneficiaries who need that treatment may have no choice but to seek care in a higher-cost setting of care. This result would be particularly problematic for beneficiaries who reside in rural areas who have fewer treatment options and who may be forced to travel further distances to receive care. We urge CMS to outline the specific proposals it intends to utilize to ensure that beneficiaries have access to their preferred treatment location.

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[4] Id.

[5] Fauzea Hussain and Adam Borden, "Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers," Avalere: Washington, D.C. (April 7, 2016), available at http://avalere.com/expertise/managed-care/insights/proposed-medicare-part-b-rule-would-reduce-payments-to-hospitals-and-some-s.

- *Stakeholder Input*: ACS CAN is concerned that because many of the policies outlined in the Part B Drug Payment Model require input from stakeholders, the timeline proposed is unattainable. In fact, as discussed in more detail below, ACS CAN urges CMS to consider additional stakeholder input to ensure beneficiary access is not compromised.
- *Need for Extensive Beneficiary Education and Outreach*: Given the size and scope of the proposed Part B Drug Payment Model, we strongly urge CMS to conduct extensive education and outreach activities specifically intended for Medicare beneficiaries. The information beneficiaries need is different – but no less important – than the information that physicians and suppliers may need to understand the changes that result from the use of the value-based pricing tools – and indeed, the overall changes contemplated by the Part B Drug Payment Model. We recommend that any communication to beneficiaries be field tested – both with beneficiaries as well as beneficiary advocate groups – to determine the most appropriate way to communicate information to beneficiaries.
- *Value-Based Pricing (VBP) Tools*: CMS proposes value-based pricing strategies that include one or more of the following specific tools: reference pricing, indications-based pricing, outcomes-based risk-sharing agreements, and discounting or eliminating patient coinsurance amounts. As CMS considers implementing the VBP tools, we urge the agency to balance the impact of the tools with advancements in treatments based on personalized medicine, including treatments based on genetic information, and issues related to side-effects and drug-to-drug interactions.
- *Clinical Decision Support (CDS) Tools*: ACS CAN appreciates CMS' recognition that clinical decision support tools can help providers choose the best treatment for the beneficiary. We urge CMS to use existing evidence-based standards, rather than creating new standards. CDS tools should be developed and utilized with both patients and providers in mind. We are disappointed that CMS missed the opportunity to clarify that the CDS tool should be developed and utilized as a treatment decision counseling tool so that a patient and his/her provider can work together to determine the best course of treatment based on the individual preferences of the patient.
- *Pre-Appeals Payment Exceptions Review Process*: While we support the addition of this new appeals process as part of the Part B Drug Payment Model, we note that beneficiaries typically do not take advantage of their appeals rights and often are only informed of their rights by their provider. We appreciate CMS' acknowledgement that the Pre-Appeals Payment Exceptions Review process cannot be used by a provider or supplier as a back-door way to impose higher cost-sharing on the beneficiary than would otherwise be required. We urge CMS to clarify that if a provider/supplier successfully appeals for a higher reimbursement amount, the beneficiary should be held harmless to the original cost-sharing amount to which she/he was otherwise required to pay.
- *Use of Contractors*: It is unclear the extent to which CMS intends to utilize contractors to administer parts or all of the Part B Drug Payment Model. Many policies raised in the proposed rule (e.g., development of the VBP tools, administration of the Pre-Appeals Payment Exceptions Review Process, beneficiary and provider education and outreach, etc.) are important functions and should not be contracted to an outside entity.
- *Evaluation*: We note that CMS intends to conduct an evaluation of the Part B Drug Payment Model. We urge CMS in its evaluation to conduct specific analysis regarding beneficiary access to oncology care. Included in this analysis should be a determination of the extent to which the

Part B Drug Payment Model has resulted in disruptions in beneficiary care and beneficiaries having to get care in higher-cost sites. We believe it is critically important for CMS to provide additional information regarding the specific quality measures it intends to use to evaluate this model and encourage the adoption of outcomes measures over process measures.

In addition, we note that CMS recently released a proposed rule implementing key parts of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),[6] which will impose a new Medicare physician payment system. We are concerned that the simultaneous implementation of the Part B Drug Payment Model and the changes imposed as a result of MACRA will create an added administrative complexity on providers and may result in the unintended consequence of exacerbating beneficiary access issues.

I. Executive Summary

B. Summary of Major Provisions

CMS proposes to implement the Part B Drug Payment Model in two phases. Phase I is intended to test the extent to which an alternative approach to the ASP add-on payment would create a financial incentive for physicians to prescribe higher value drugs. CMS proposes to assign all providers within a given geographic unit into two arms. One arm would constitute the control group whereby providers and suppliers would continue to receive the ASP + 6 percent add-on payment. Providers and suppliers in the second arm would receive a reimbursement of ASP + 2.5 percent add-on + a flat fee. Under Phase II, providers and suppliers would be further divided into two arms which would permit the use of value-based purchasing tools.

The preamble includes a helpful chart depicting the proposal:

TABLE 1: Summary of the Proposed Model

Phase 1 – ASP+X (no earlier than 60 days after display of final rule, Fall 2016)	Phase 2 – VBP (no earlier than January 2017)
ASP+6% (control)	ASP+6% (control)
	ASP+6% with VBP Tools
ASP+2.5% and Flat Fee Drug Payment	ASP+2.5% and Flat Fee Drug Payment
	ASP+2.5% + Flat Fee Drug Payment with VBP Tools

Note: Primary Care Service Areas (which are clusters of ZIP codes that reflect primary care service delivery) would be randomly assigned to each model test arm and the control group. The assigned PCSAs would not include ZIP codes in the state of Maryland where hospital outpatient departments operate under an all-payer model.

[6] On April 27, 2016, CMS issued a Notice of Proposed Rulemaking. Centers for Medicare & Medicaid Services, Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models, available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-10032.pdf. The proposed rule is scheduled to be published in the *Federal Register* on Monday, May 9, 2016.

1. Model Overview

The proposed rule states that "[i]mplementation [of the Part B Drug Payment Model] will be on or after August 1, 2016."[7] According to the preamble CMS "propose[s] to implement this first phase of the overall model no earlier than 60 days following display of the final rule."[8] The proposed rule states that "Phase II will be implemented on or after January 1, 2017."[9]

Proposed timeline: ACS CAN is extremely concerned that this entire plan and implementation timeline is unrealistic given the magnitude and scope of the proposed Part B Drug Payment Model and should not be implemented as outlined under the proposed rule. As discussed in more detail below, ACS CAN has serious concerns with some of the proposed policies contained in the Part B Drug Payment Model and we urge CMS to address these concerns before it even considers implementation of any new payment model.

If Phase I begins on August 1, 2016 (as stated in the proposed rule) and the first phase of the model begins 60 days after display of the final rule[10] (as stated in the preamble) it suggests that CMS considers it possible to release a final rule (if only for display purposes) by May 31, 2016. In order to accomplish this goal, CMS only would have three weeks (between May 10th and May 31st) to review and synthesize all of the stakeholder comments, make modifications to the proposed rule based on stakeholder recommendations, and acquire the necessary administrative clearance in order to release a final rule before June 1st, which is 60 days before the earliest implementation date for Phase I. Given the size and scope of the Part B Drug Payment Model, it is anticipated that CMS will receive numerous detailed comments, which will further impede CMS' ability to meet the proposed timeframe.

In addition, we are concerned with CMS' proposal to begin Phase II of the Part B Drug Payment Model as early as January 1, 2017 (less than seven months after the close of the proposed rule's comment period). Phase I represents the most significant change in Part B drug payment policy in over a decade. Given the magnitude of the proposed rule and the need for significant beneficiary, provider, and supplier education and outreach about the policy change, we strongly urge CMS to consider delaying implementation of Phase II until the agency has an opportunity to fully implement and conduct at least some initial evaluation of the first phase of the proposal. We believe it prudent to allow additional time for Phase II to be implemented in order to allow CMS the opportunity to more fully develop the details of the VBP tools that could be used as well as to provide a more robust opportunity for public comment.

The scope and breadth of this particular model requires CMS to establish a more realistic timeframe for implementation. This would ensure that the model is well designed such that it avoids – or at the very least minimizes – unintended consequences for cancer patients.

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[7] § 511.205(d)(1).

[8] 81. Fed. Reg. at 13232.

[9] § 511.205(d)(2).

[10] We note that it can often take days – if not weeks – for a display copy of a rule to be published in the *Federal Register*. For example, the MACRA proposed rule was released by CMS twelve days before publication in the *Federal Register*. At the very least, any deadlines should be imposed based on the date of publication in the *Federal Register* and not the availability of the display of the rule.

Potential for increased beneficiary cost-sharing: According to an analysis by Avalere,[11] under the Part B Drug Payment Model, Part B products that cost less than $480 would receive higher payments relative to the current reimbursement structure. Beneficiaries without supplemental coverage pay 20 percent cost-sharing for Part B services, and thus their cost-sharing would increase for lower cost drugs. Even beneficiaries with supplemental coverage may not necessarily be immune from increased cost-sharing. For example, beneficiaries with Medicare supplemental coverage could see these premiums increase. Thus, as the CMS model seeks to incentivize physicians to prescribe higher-value Part B drugs by providing a higher reimbursement, it could create a disincentive for beneficiaries to take higher-value drugs because they would have higher cost-sharing compared to a lower-value drug. We urge CMS to examine additional ways to ensure that while physicians are incentivized toward higher value drugs, similar incentives are provided for beneficiaries as well.

Need for beneficiary education and outreach: In recent years, there have been significant improvements to the Medicare program including the creation of the Medicare Prescription Drug Benefit and the important changes included in the Affordable Care Act (including the closure of the Medicare Part D donut hole, coverage of additional preventive services, and policies that have extended the solvency of the Medicare Part A Trust Fund). While these policies have significantly improved the quality of life and care for Medicare beneficiaries, we have also learned that beneficiaries are vulnerable to misinformation absent extensive education and outreach specifically geared to that demographic.

Effective education and outreach about the Part B Drug Payment Model cannot begin until the policy has been finalized. We do not believe that 60 days will provide sufficient opportunity for CMS – or any stakeholder – to develop, test, and implement an extensive and well-designed beneficiary education and outreach program, particularly given the complexity of the issue. We urge CMS to engage in significant education and outreach specifically targeted to beneficiaries, providers, and suppliers before implementing the Part B Drug Payment Model. This education and outreach may identify additional guidance that would be needed before proceeding with the implementation of the model.

Stakeholder involvement: We note that the Center for Medicare and Medicaid Innovation (CMMI) has successfully developed new models of care – including the Oncology Care Model (OCM) and the Medicare Care Choices Model (MCCM) which are both at various stages of implementation. We have very much appreciated CMMI's extensive outreach to the stakeholder community for both of these models as well as other models being tested.

Given that CMS is using the demonstration authority granted to CMMI to conduct the Part B Drug Payment Model, we are deeply disappointed that the agency failed to provide significant stakeholder input prior to the release of the proposed rule. Stakeholder input prior to the formal rulemaking process allows CMMI the opportunity for open discussion and dialogue which we believe results in models that are more defined and targeted to achieve the Triple Aim. By not engaging in an extensive stakeholder outreach process prior to the introduction of the proposed rule, we believe CMS missed out on an opportunity to solicit feedback and address concerns that could have resulted in a better proposal.

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[11] Fauzea Hussain and Adam Borden, "Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers," Avalere: Washington, D.C. (April 7, 2016), available at http://avalere.com/expertise/managed-care/insights/proposed-medicare-part-b-rule-would-reduce-payments-to-hospitals-and-some-s.

2. Model Scope

CMS proposes that the Part B Drug Payment Model run for five years.[12] The preamble states CMS' expectation that Phase II could take several years to fully implement, though at the same time CMS' "goal is to have both phases of the model in full operation during the last three years of the proposed five-year duration to fully evaluate changes and collect sufficient data."[13]

ACS CAN recognizes that CMS' proposed five-year duration is consistent with other CMMI models. While we appreciate CMS' intention to gain sufficient data in order to fully evaluate the model, we urge CMS to consider allowing additional time to implement the first phase of the Part B Drug Payment Model before proceeding to the second phase. As discussed in more detail below, ACS CAN has concerns with several of the policies contained in both Phase I and Phase II. It will take time for beneficiaries, providers, and suppliers to adjust to any new payment model. Also, as discussed above, ACS CAN believes the scope of the Part B Drug Payment Model must be dramatically reduced.

II. Participation

B. Proposed Drugs Paid Under Part B To Be Included in the Model

With limited exceptions, CMS proposes to include all Part B drugs in the Part B Drug Payment Model. One notable exception includes Part B covered vaccines. With respect to drugs that have been reported by the FDA to be in short supply, CMS proposes to pay for those drugs using the current ASP + 6 percent payment methodology and seeks comment on alternate approaches.

ACS CAN supports CMS' proposal to exclude influenza, pneumococcal pneumonia and hepatitis B vaccines from the Part B Drug Payment Model. ACS CAN is supportive of the recognition of the value of preventive services such as these vaccines which, when used properly, help to keep beneficiaries healthier and improve their quality of life. We note, however, that the text of the proposed rule[14] appears to contain a misprint in that it refers to section 1862(s)(10) rather than section 1861(s)(10). We urge CMS to correct this error when promulgating the final rule.

Drugs in short supply: CMS proposes that for drugs determined to be in short supply, CMS would continue paying for those drugs using the existing statutory methodology (e.g., ASP + 6 percent). ACS CAN is pleased that CMS expressed concern about how to address drugs that are in short supply and recognized the need to provide a safeguard to preserve access to these drugs. We note, however, that there are many different factors that cause drugs to be in short supply. It is unclear whether the proposed policy will ensure whether either payment methodology will affect the primary factors leading to drug shortages, but we encourage CMS and FDA to closely monitor any potential effects of the demonstration project on drug supplies. We encourage CMS to work with the FDA and other stakeholders to develop a policy to address any potential supply shortages.

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[12] § 511.205(d)(1).
[13] 81 Fed. Reg. at 13232.
[14] § 511.200(c)(3).

C. Proposed Participants, Selected Geographic Areas, and Sampling

CMS proposes to require all providers and suppliers who furnish Part B drugs within a select geographic area to participate in the Part B Drug Payment Model. CMS contemplated using several different geographic units and ultimately proposed to use the Primary Care Service Area (PCSA) as the most appropriate geographic unit. Exempting providers in Maryland due to its unique waiver system, CMS estimates where would be potentially 7,048 PCSAs used in the Part B Drug Payment Model. When both Phase I and Phase II of the Part B Drug Payment Model are implemented CMS expects approximately 1,700 PCSAs in each of the control and three test arms.

ACS CAN agrees with CMS' concern that using states as the appropriate geographic unit would be problematic given that there is significant variation in size and numbers of beneficiaries among the states. Some states are so large as to make evaluation and monitoring too cumbersome a process.

Unlike most other CMMI demonstrations, CMS proposes that the Part B Drug Payment Model be mandatory and national in scope. Given the various stakeholder concerns expressed regarding the potential impact of the Part B Drug Payment Model, we urge CMS to reconsider implementing this model on a national scope. Rather, CMS could identify a number of targeted geographic areas in which to test a new payment model.

In addition, it is unclear from the proposed rule the extent to which contiguous PCSAs would be assigned to the same arm of the Part B Drug Payment Model. If contiguous PCSAs are randomly assigned to different payment models, it seemingly would be possible for a large group practice that operates in different PCSAs to direct a Medicare beneficiary to the practice location that offers the greater financial incentive to the provider. This diversionary practice could result in higher cost-sharing for the beneficiary depending on the reimbursement model being used within the PCSA. The beneficiary could also face transportation issues accessing the alternate site of care. We note that some providers operate in multiple states and thus this potential diversionary practice could occur regardless of geographic area chosen.

While similar diversionary practices could occur regardless of the geographic unit, we urge CMS to establish safeguards to ensure that beneficiaries are not directed to a particular site of care depending on the more advantageous reimbursement structure provided under the Part B Drug Payment Model. For example, CMS could monitor the extent to which a beneficiary receives care at more than one PCSA. This evaluation may be challenging given that CMS proposes to assign providers to the PCSA using their National Provider Identifier (NPI). While all solo physicians are required to have their own NPI, physicians who are part of a large group practice are not required to have their NPI and may use the NPI of the large group practice.

However, to the extent that multiple beneficiaries are receiving care from the same provider (identified by the billing NPI) at two or more PCSAs (particularly if these claims are for the same drug), CMS should examine the extent to which beneficiaries are being diverted to different sites of care to be more financially advantageous to the provider. In such instances, CMS should make clear to the provider that diversionary tactics are not permitted.

III. Payment Methodology

A. Phase I: Proposed Modifications to the ASP Add-On Percentage for Drugs Paid Under Part B

In Phase I of the Part B Drug Payment Model, CMS proposes to assign providers and suppliers into two arms: the first would be the control group who would continue to receive ASP + 6 percent and the second group would receive ASP + a 2.5 percent add-on payment + a flat fee (which under the CMS proposal would be $16.80 per drug per day). While the flat fee would be updated annually based on the Consumer Price Index – Medical Care (CPI-MC), CMS proposes to keep the 2.5 percent add-on constant over the duration of the Part B Drug Payment Model. Phase I is intended to be budget neutral across all Part B drugs.[15]

ACS CAN understands CMS' attempt to address rising cost of prescription drugs. However, we are concerned the implementation of Phase I of the Part B Drug Payment Model could negatively impact cancer patients' ability to access their Part B drugs in their preferred setting of care. According to CMS' analysis, some providers (like primary care) will see an increase in their Part B reimbursement and some providers (like those providing specialized services such as oncology) will see a decrease in their reimbursement. While overall these changes in reimbursement may be budget neutral in Phase I, we are concerned that the shift in reimbursement – from specialists like oncologist to primary care – may fundamentally shift the administration of health care services.

We want to ensure that any payment model incentivizes beneficiaries to receive the right care, at the right time, and in the right setting. While we are supportive of primary care, a cancer patient will rely on her/his oncologist for most – if not all – of her/his health care needs during active treatment. Given a variety of factors – including the frequency with which patients in active cancer treatment interacts with their oncologists, the potential side effects of the medication, etc. – the oncologist often serves as the care coordinator for an individual in active treatment before the beneficiary transitions back into primary care.

ACS CAN is concerned that while CMS' proposal may be budget neutral in the aggregate, the proposal's impact has the potential to negatively impact oncology services. The preamble acknowledges that Phase I "has the overall effect of modestly shifting money from hospitals and specialties that use higher cost drugs … to specialties that use lower cost drugs."[16] According to one analysis, more than half of the payment reductions provided for under the proposed rule would come from 10 drugs (7 of which are used to treat cancer).[17] In fact, CMS' impact analysis estimates that hematology/oncology will see a 0.4 percent reduction in their Medicare reimbursements while medical oncology will see a 0.5 percent reduction in their Medicare reimbursements.[18] CMS notes that these estimated reductions do not take into account reductions applied to Medicare payment under sequestration. According to another

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[15] 81 Fed. Reg. at 13233.

[16] Id.

[17] Fauzea Hussain and Adam Borden, "Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers," Avalere: Washington, D.C. (April 7, 2016), available at http://avalere.com/expertise/managed-care/insights/proposed-medicare-part-b-rule-would-reduce-payments-to-hospitals-and-some-s.

[18] CMS, Table 2 – Impact of Part B Drug Payment Model on Hospitals, Practitioners, and Pharmacies by Specialty, 81 Fed. Reg. at 13255.

analysis, oncologists could see payment reductions of 14 percent.[19] We are concerned that depending on the manner and amount of the reimbursement reduction, beneficiaries may experience problems accessing oncology care. We note that in its June 2015 report, the Medicare Payment Advisory Commission (MedPAC) presented a similar proposal to revise the Part B payment methodology as outlined in Phase I, but even the Commission noted the uncertain effects of these payment changes on physician behavior and beneficiary access.[20]

ACS CAN highly values the role of primary care providers, however, the services they provide are not interchangeable with the specialized services provided by oncologists. As previously noted, that while a beneficiary is undergoing cancer treatment, the oncologist is most likely to be that beneficiary's primary care provider until the oncology services are finished and the individual transitions back to primary care.

Higher-cost settings of care: While the Part B Drug Payment Model seeks to reduce overall Part B costs, ACS CAN is concerned the model as proposed could result in the unintended consequence of shifting care to higher-cost settings, thus resulting in increased – not decreased – Part B costs. To the extent that a provider's cost for acquiring a Part B drug exceeds the reimbursement provided for that drug (e.g., the provider is "underwater" with respect to the drug), the provider will be unable, or unwilling, to administer the drug in the physician office setting. In such instances, the provider could send the beneficiary to the hospital outpatient department to obtain treatment.

Shifting the site of care to the hospital setting results in an undue burden on the beneficiary. First, the beneficiary's cost-sharing will be higher in the hospital setting relative to the physician's office setting. When services are provided in a physician's office, Medicare makes a single payment for the service, but when services are provided in a hospital Medicare makes two payments: one to the facility and one to the provider. Not only would the beneficiary's cost-sharing be higher, but moving the site of care to the hospital setting increases costs for the overall Medicare program – the antithesis of one of the stated goals of the Part B Drug Payment Model.

In addition, many beneficiaries prefer to receive treatment in the community setting and not the hospital setting. Often it can be challenging for the beneficiary to obtain access to a hospital. Depending on the geographic area, beneficiaries may have to travel a far distance in order to obtain care in the hospital setting. For a cancer patient in active treatment, this creates an additional burden. Cancer patients are told not to drive following treatment because chemotherapy leaves patients fatigued, and some of the medications administered along with chemotherapy tend to make patients drowsy and unable to drive themselves or use public transportation. In addition, many cancer patients – particularly those with low or limited incomes – may not own a vehicle, be unable to afford public

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[19] Fauzea Hussain and Adam Borden, "Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers," Avalere: Washington, D.C. (April 7, 2016), available at http://avalere.com/expertise/managed-care/insights/proposed-medicare-part-b-rule-would-reduce-payments-to-hospitals-and-some-s.

[20] In its June 2015 report, MedPAC explored two policy options: (1) 100 percent of ASP + $24 per drug per administration day, and (2) 102.5 percent of ASP + $14 per drug per day. The MedPAC reported noted that "it is difficult to know the extent to which the percentage add-on to ASP has the potential to affect drug prescribing patterns and the resulting spending levels." MedPAC, Report to the Congress: Medicare and the Health Care Delivery System, June 2015, Ch. 3 at 69.

transportation, or do not live in an area where public transportation is readily accessible. Often patients do not have a family member or friend who is available to provide regular assistance with transportation. Individuals with cancer need regular access to care and cancer treatment services and when that access is disrupted the effectiveness of the treatment could be jeopardized and the individual's chance of survival could be significantly reduced.

Potential for "brown bagging": ACS CAN is concerned the proposed Part B Drug Payment Model creates an incentive for providers to encourage the practice of beneficiaries obtaining their Part B drugs at the pharmacy and then carrying the medication to the physician's office for administration (so-called "brown bagging"). In essence, brown bagging shifts coverage from Part B to Part D, thus exposing some beneficiaries to additional cost-sharing depending on his/her Medicare Part D plan.

Brown bagging poses a number of challenges for Medicare beneficiaries. It requires beneficiaries to make a separate trip to the pharmacy to obtain their drugs. As discussed above, beneficiaries in active cancer treatment may be too sick to drive to the pharmacy to obtain the drug. While many cancer patients have a caregiver who may be able to obtain the medication at the pharmacy, not all cancer patients have this level of support.

In some cases, the beneficiary may be able to obtain the medication through mail order pharmacy, though this too creates challenges for the beneficiary. While mail order can be a viable option for the administration of medications used for chronic conditions, it is not necessarily an appropriate option for physician administered drugs. A drug shipped through the mail may get lost in transit, may not be received on time, or may be inadvertently damaged during shipment. In some instances, the dosing amount of the drug may need to be slightly changed before the drug is administered to the patient. Moreover, some Part B medications may require special handling (such as refrigeration) which may make mail order an unwise alternative.

We urge CMS to make clear in its final rule that brown bagging is prohibited. We also urge CMS to engage in extensive monitoring to determine the extent to which "brown bagging" occurs. Further, as part of its evaluation of the Part B Drug Payment Model – discussed in more detail below – we urge CMS to identify specific evaluation tools it will implement to determine the extent to which this practice is being utilized.

B. Phase II: Applying Value-Based Purchasing Tools

1. Introduction

In Phase II, CMS proposes to implement Value-Based Purchasing (VBP) tools for Part B drugs using value-based pricing and clinical decision support tools. The preamble notes that the application of VBP tools "to drugs that are typically paid for under a medical benefit, such as physician administered drugs, has the potential to result in significant savings."[21] CMS notes that it intends to implement the VBP tools through a contractor.

[21] 81 Fed. Reg. at 13242, citing Dorhalt M. Advancing Drug Trend Management in the Medical Benefit. Managed Care. June 2014. http://managedcaremag.com/archives/2014/6/advancing-drug-trend-management-medical-benefit.

Potential for cost-shifting: When properly utilized to ensure beneficiary access, some VBP tools can improve quality while lowering health care costs. Some of the VBP tools referenced in the Managed Care article cited in the preamble may be worthy of consideration. However, we are concerned that the article cited by CMS suggests that one way to reduce prescription drug costs under the medical benefit would be to "mov[e] specialty medications from the medical benefit to the pharmacy benefit where appropriate."[22] While this policy could result in savings for commercial plans, in the Medicare context this would result in shifting prescription drugs from Part B coverage to Part D coverage. Part B spending would decrease, but there would be a corollary increase in Part D spending.

This policy could negatively impact cancer patients, depending on the coverage provided by their Medicare Part D plan. Whereas Medicare Part B provides coverage for all physician-administered prescription drugs that are approved by the FDA, the Medicare Part D program is operated exclusively through private plans – all of which provide coverage through the use of a drug formulary. To the extent that drug coverage is moved from Part B to Part D, beneficiaries may experience higher cost-sharing depending on the Part D plan coverage or could encounter access problems if their Part D plan does not provide coverage for the specific drug. While we recognize that Medicare beneficiaries could file an exception to obtain coverage under their Part D plan, this does not guarantee that coverage will be granted.

Use of a contractor: The proposed rule states that "[o]ne or more contractors will be utilized to implement CMS approved VBP tools."[23] While we recognize that CMS uses contractors for a variety of purposes, we urge CMS to provide additional information regarding how it intends to use contractors for the Part B Drug Payment Model.

While the proposed rule states that contractors would be used to implement VBP tools, it is unclear the extent to which CMS would utilize contractors to develop the VBP tools. We urge CMS to conduct the development of the VBP tools (with public input as discussed below) and to not contract out this important function to an outside entity.

To the extent CMS intends to contract with multiple entities it is not clear whether the contracts would be awarded based on each arm of the Part B Drug Payment Model (e.g., CMS would initially contract with two entities for Phase I and then conceivably at least two additional entities for Phase II). The concern with this approach is that there could be significant variation between the contractors with respect to the use of VBP tools. Thus, beneficiaries in one geographic unit (e.g., the proposed PCSA) could be subject to a different interpretation of a given VBP tool than a similarly situated beneficiary in another geographic unit.

Alternatively, CMS could award contracts based on specific VBP tools (e.g., implementing the use of value-based pricing based on the clinical effectiveness of a drug). While this approach would better ensure consistency across all Part B providers, it could prove operationally challenging to ensure that the combination of one or more VBP tools do not create unintended access problems for beneficiaries.

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[22] Dorhalt M. Advancing Drug Trend Management in the Medical Benefit. Managed Care. June 2014. http://managedcaremag.com/archives/2014/6/advancing-drug-trend-management-medical-benefit.

[23] § 511.205(e).

It also is unclear whether CMS intends for the contractor(s) to be responsible for evaluating and monitoring any potential access problems a beneficiary may encounter as a result of the Part B Drug Payment Model. If that is CMS' intent, we urge greater clarification regarding the specific methods the contractor(s) will utilize to ensure that beneficiaries have access to their Part B covered drugs.

Given that the VBP tools will be implemented via contractor(s), we question whether it is CMS' intent that these entities bear responsibility for collecting and addressing any beneficiary complaints or concerns that may arise as a result of the use of the tools. While CMS intends to provide a Pre-Appeals Payment Exception Review Process – discussed in more detail below – beneficiaries may have questions or concerns about the use of the VBP tools outside the limited scope of the Pre-Appeals Payment Exception Review Process (e.g., beneficiaries may have questions or concerns raised after the submission of a claim subject to a VBP tool). If it is CMS' intention to use contractor(s) for the appeals process, it is unclear how a beneficiary will be made aware of how to contact the contractor(s) – which may prove challenging if CMS intends for multiple contractors to operate within the same geographic area.

While CMS recognizes in the proposal the need to conduct education and outreach regarding the changes implemented under the Part B Drug Payment Model, it is unclear whether the contractor(s) responsible for implementing the VBP tools also will be responsible for providing this necessary education and outreach. Presumably the contractor(s) will conduct education and outreach to physicians and suppliers who are impacted by the VBP tool. However, we strongly urge CMS to provide education and outreach to beneficiaries as well. The information beneficiaries need is different – but no less important – than the information that physicians and suppliers may need to understand the changes that result from the use of the VBP tool – and indeed, the overall changes contemplated by the Part B Drug Payment Model.

The preamble also is silent with respect to what happens if a given contract is terminated (either due to cause or because the contractor is unable or unwilling to perform specified contract functions). We are concerned that if a contract is terminated within the demonstration period, it could create a gap in vital functions of the Part B Drug Payment Model particularly if, as discussed above, the contractor is responsible for beneficiary education and outreach and/or implementation of the Pre-Appeals Payment Exception Review Process. The final rule should specify the action CMS would take in the case of contract termination.

Finally, given the proposed timeframe, we question whether CMS will have sufficient time to be able to finalize the rule, draft a detailed scope of work, create an open contractor bidding process, and select one or more contractors before the beginning of Phase II, which according to the proposed rule could be as early as January 1, 2017. Thus, we reiterate our concern with the proposed timeframe and urge CMS to provide additional time before implementing Phase II.

2. Value-Based Pricing Strategies

CMS proposes value-based pricing strategies that include one or more of the following specific tools: reference pricing, indications-based pricing, outcomes-based risk-sharing agreements, and discounting or eliminating patient coinsurance amounts. As CMS considers implementing the VBP tools, we urge the agency to balance the impact of the tools with advancements in treatments based on personalized medicine, including treatments based on genetic information, and issues related to side-effects and drug-to-drug interactions.

Opportunity for public comment on the proposed VBP tools: CMS intends to finalize the implementation of specific tools for specific HCPCS codes after soliciting public input on each proposal which it will post on the CMS website. CMS notes that it will allow 30 days for public comment and will provide a minimum of 45-days public notice before implementation.

ACS CAN is concerned that the proposed public comment period for feedback on the VBP tools is insufficient for a number of reasons. First, depending on how CMS proposes to apply a specific VBP tool to a particular drug, the use of the VBP tool can raise clinical and other concerns. Thus, a longer comment period may be necessary in order to provide the public with sufficient opportunity to review the proposal and provide meaningful comment. Moreover, it is unclear from the preamble whether the 30-day comment period would consist of 30 business days, or 30 calendar days – the former would provide for a greater opportunity to review and submit more robust comments.

Similarly, we are concerned with CMS' proposal to provide a minimum of 45 days "notice" before implementation of a VBP tool. We do not believe this timeframe is adequate to allow CMS to properly educate beneficiaries, providers, and suppliers about the proposed VBP tool. In addition, we question whether the 45-day notice period would be sufficient to permit contractors, manufacturers, suppliers, physicians, and other stakeholder the opportunity to update their IT systems and/or make other necessary changes.

We are concerned with CMS' intent to implement the use of VBP tools through sub-regulatory guidance. Given the potential impact of a given tool on a beneficiary's access to a medically necessary Part B drug, we do not believe that simply posting the proposed VBP tools on the CMS website provides a sufficient opportunity for public comment. It is unclear from the preamble whether comments will be submitted via an open process (like regulations.gov) whereby comments submitted are made public, or whether CMS will receive comments similar to its collection of comments through other sub-regulatory guidance (like comments on the Medicare Advantage-Prescription Drug Plan (MA-PDP) call letter) where comments received are not made publicly available. We strongly urge CMS to make publicly available any comments it receives through this process. This will allow stakeholders the opportunity to review others' comments so that a more robust dialogue can exist among all interested parties.

Use of VBP tool by HCPCS code: The preamble notes that CMS does "not intend to apply the [VBP] tools to all Part B Drugs; we plan to implement the use of the tools in a limited manner for certain drug HCPCS codes after considering these tools' appropriateness to specific Part B drugs within those codes."[24]

[24] 81 Fed. Reg. at 12243.

ACS CAN appreciates CMS' clarification that not all Part B drugs will be subject to VBP tools. For example, unlike some Part B drugs, oncology care can be very specific and only one drug may exist to treat an individual's specific cancer. Thus, reference-based pricing or other tools may not be appropriate in those instances.

When determining which VBP tool(s) should be implemented, we urge CMS to begin with drug categories for which there are many different drug options within one category or class and for which there exists extensive research regarding the comparable efficacy of the drugs within the class.

Use of pharmacy utilization management tools: The preamble suggests that CMS could consider allowing the use of certain formulary tools that are commonly used by plans to steer utilization management of particular drugs.

We are pleased with a number of policies that exist in the Medicare Part D program that protect beneficiary access to medically necessary drugs. Beneficiaries in Medicare Part D are permitted to appeal the formulary tier and apply to move a drug to a lower-cost tier when access to the higher-tiered drug is medically necessary. Medicare Part D also has requirements in place regarding which drugs can be placed in the highest formulary tier. Medicare Part D plans are also limited in their ability to switch their formularies mid-year. Part D also has adopted a policy of classes of clinical concern (e.g., the six protected classes) whereby beneficiaries must have access to all or substantially all drugs within these six classes of drugs.

To the extent that CMS will allow the use of VBP tools that create a formulary or mirror the utilization management tools commonly utilized in the Part D benefit, we urge CMS also to adopt appropriate beneficiary protections as provided in Part D.

Potential for a discriminatory benefit design: We are concerned that some of the VBP tools that may be considered could result in a potential discriminatory benefit design. For example, to the extent that CMS would permit the creation of a formulary for Part B drugs and that formulary placed all drugs to treat a specific disease or condition on the highest formulary tier, such a design could constitute a discriminatory benefit design.[25]

We strongly urge CMS to ensure that the design and utilization of any VBP tool – either the tool itself or in combination with one or more VBP tools – does not result in a discriminatory benefit design. In fact, in reviewing any VBP tool, we urge CMS to make a specific determination that the use of the tool would not constitute a discriminatory benefit design prior to allowing the use of the specific VBP tool.

While HHS has yet to publish the final rule implementing section 1557 of the Affordable Care Act (ACA), we are concerned that the proposed rule would not apply to physicians who receive Medicare Part B payments but no other funding.[26] If this provision is included in the final rule implementing ACA section 1557, we urge CMS to specifically note in the final regulation implementing this model that the nondiscrimination protections provided under ACA section 1557 would apply to any and all VBP tools utilized under this model.

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[25] See Letter from Christopher W. Hansen, President, American Cancer Society Cancer Action Network, to Sylvia Burwell, Secretary, Department of Health and Human Services (Nov. 9, 2015).

[26] See, Frank M, Section 1557 of the ACA Should Not Allow Some Physicians to Discriminate, Health Affairs Blog, Jan. 6, 2016, available at http://healthaffairs.org/blog/2016/01/06/section-1557-of-the-aca-should-not-allow-some-physicians-to-discriminate/.

Use of reference-based pricing: One VBP tool CMS proposes to implement is providing equal payment for therapeutically similar drug products (e.g., reference pricing). CMS explained its vision of this policy in the preamble:

> A benchmark is set based on the payment rate for the average price for drugs in a group of therapeutically similar drug products, the most clinically effective drug in the group, or another threshold that is specifically developed for such drug products, like a specific percentile of the current price distribution; and all drugs from the group are then paid based on this amount. … Individual characteristics of each group of drugs considered for reference pricing, such as relative effectiveness demonstrated in competent and reliable scientific evidence, would be taken into account before selecting a benchmark rate.[27]

ACS CAN believes the use of reference-based pricing as proposed by CMS would not be suitable for all Part B drugs. We have concerns about the implementation of this policy with respect to oncology drugs – most notably those medications that are developed through precision medicine or personalized medicine. By better understanding the molecular alterations that cause a given cancer, researchers are able to develop targeted therapies aimed at specific genetic mutations that drive that cancer.[28] 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. Thus, we urge CMS to ensure the Part B Drug Payment Model does not impede access to drugs that are designed to treat beneficiaries who possess specific genetic markers.

Prohibition of balance billing for reference pricing: CMS proposes that any version of reference pricing implemented under this model would prohibit balance billing of the beneficiary for any difference in pricing.[29]

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[27] 81 Fed. Reg. at 13243.

[28] 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 involved 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, available at http://www.acscan.org/content/wp-content/uploads/2014/04/Patient-Expectations-and-Access-Barriers.pdf.

[29] "Medicare providers and suppliers may not bill the beneficiary for any difference in pricing between the benchmark rate and the statutory payment rate or the provider or supplier's charge for the drug prescribed." § 511.305(1)(i).

ACS CAN supports CMS' inclusion of this important beneficiary protection. If the intent of reference-based pricing is to encourage the use of high-value services, beneficiaries should not be asked to pay more for a lower-value drug. The decision of which drug a beneficiary should use is largely driven by the physician prescriber. Medicare beneficiaries should not be asked to pay more in the event that their prescriber chooses a drug that is above the reference price.

Indications-based pricing: CMS proposes to vary prices for a given Part B drug based on the varying clinical effectiveness for different indications. The preamble uses the example of a drug used to treat two different cancers.[30] If clinical trial data demonstrated that the drug's effectiveness was no better than an existing treatment for one type of cancer, but better than the existing treatments for another type of cancer, the indications-based pricing tool would result in lower payments when the drug is used to treat the first type of cancer and higher payments when the drug is used to treat the second cancer. The preamble notes that the Institute for Clinical and Economic Review (ICER) is in the process of producing reports on high-impact drugs.

ACS CAN believes that indications-based pricing, if used appropriately, may be suitable in oncology care. 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 medication can be challenging to manage and few treatment options may exist. This is why it is imperative that any treatment decision be made through informed decision making so the beneficiary – in consultation with her/his oncologist – can choose the treatment path that best meets her/his needs.

In addition, we urge CMS not to rely solely on ICER for its determination of what constitutes clinical effectiveness. We are concerned that some of ICER's evaluations have focused too much on the cost of a given treatment and fail to accurately incorporate the long-term health outcome benefits and quality associated with the treatment. We strongly urge CMS to rely on multiple sources for the determination of clinical effectiveness.

Linking health outcomes with payment: Another tool under consideration in the Part B Drug Payment Model would be to allow CMS to enter into voluntary contracts with manufacturers to link health care outcomes with payment. Any outcomes-based risk-sharing agreements would require clearly defined outcomes goals.

ACS CAN sees some value in this proposed VBP tool insofar as it could reward innovation that leads to the defined health outcome. Unfortunately, cancer care lacks a robust field of outcomes measures. According to Avalere, there are 305 cancer measures currently in use, but 85 percent of them are process not outcomes measures.[31] We are pleased there is a recognition of cancer as a national priority for quality improvement[32] and as such there needs to be more attention paid to the gaps in oncology measures so a tool like linking outcomes to payment is possible.

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[30] 81 Fed. Reg. at 13243.

[31] Avalere, Quality Measures Addressing Cancer Care, April 2015, available at http://avalere.com/expertise/life-sciences/insights/quality-measures-and-cancer-care-what-you-should-know.

[32] Id.

Waiving beneficiary cost-sharing: CMS proposes implementing a VBP strategy "that involves discounting or eliminating patient coinsurance amounts for services that are determined to be high in value in an attempt to tailor incentives."[33] Under this proposed policy, CMS would have the authority to waive beneficiary cost-sharing from the current 20 percent to a value that is less than 20 percent and could be waived completely.[34]

ACS CAN supports this policy which is intended to ensure that beneficiaries are financially incentivized to utilize higher-value drugs when available and medically appropriate.

We urge CMS to provide specific details regarding what constitutes a "high-value" drug. It is not clear whether a drug is determined to be "high-value" relative to other drugs available in the marketplace or whether the value of the drug is determined relative to other Medicare-covered products and services. For example, a cancer drug that has been clinically shown to be effective at treating a specific cancer, thus eliminating the need for additional surgery and/or radiation services could be considered high in value. In making the determination of what constitutes a "high-value" drug, we urge CMS to examine all factors, including the availability of similar Part B drugs, costs for other Medicare-covered services, and value to the beneficiary.

Beneficiary cost-sharing: Similarly, the preamble notes that CMS will not exceed the 20 percent cost-sharing for low-value drugs. We appreciate and support CMS' clarification that the policy does not intend to increase cost-sharing for beneficiaries who receive lower-value drugs. However, as a practical matter given that beneficiaries' cost-sharing is represented as a percentage of the cost of the Part B drug, as CMS increases provider reimbursement beneficiaries will pay a higher cost-sharing.

Educational activities: The preamble notes that CMS "would also engage in educational activities to support implementation and testing of the value-based pricing strategies."[35]

ACS CAN urges CMS to not only focus these activities on providers and suppliers, but also to develop an educational plan specifically designed and targeted to Medicare beneficiaries. We recommend that any communication to beneficiaries be field tested – both with beneficiaries as well as beneficiary advocate groups – to determine the most appropriate way to communicate information to beneficiaries.

Potential safeguards: CMS recognizes that "the value-based pricing tools discussed here could pose a risk of abuse if not properly structured and operated."[36] CMS therefore seeks comment on potential safeguards that could be implemented to ensure the intent of the policy is not undermined.

ACS CAN appreciates CMS' recognition of the need for additional safeguards to ensure that beneficiary access is protected. As discussed in more detail below, we strongly urge CMS to provide additional beneficiary safeguards. We strongly urge CMS to include quality measures as a component of the Part B Drug Payment Model. Dr. Conway has indicated that CMS is inclined to adopt specific quality measures – including patient-reported outcomes measures and measures that have yet to be developed[37] – and we urge CMS to provide additional information regarding the measures CMS intends

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[33] 81 Fed. Reg. at 13244.
[34] Id.; § 511.305(1)(iv).
[35] 81 Fed. Reg. at 13244.
[36] Id.
[37] Remarks from Dr. Patrick Conway, Acting Principal Deputy Administrator, Deputy Administrator for Innovation and Quality, and Chief Medical Officer, Centers for Medicare and Medicaid Services, Public Forum on the Medicare

to use. We also urge CMS to clarify the extent to which CMS intends to develop its own measures, or whether it will rely on a multi-stakeholder consensus-building entity like the National Quality Forum (NQF) to develop new measures.

Similarly, as discussed above, the role of the contractor(s) has not yet been clearly defined and it is unclear the extent to which a contractor(s) will be tasked with developing one or more quality measures. Given the rigor required to develop and implement high-quality measures, ACS CAN urges CMS to utilize measures developed from a multi-stakeholder consensus entity like the NQF.

Moreover, we urge CMS to establish a clear, standard quality measure set – based on outcomes, not process measures – that will be used across all arms of the Part B Drug Payment Model. This measure set should be designed to ensure that beneficiary access is not compromised by initiatives utilized in the model. In addition, CMS should develop standard quality measures to be used in each arm of the model as well as quality measures for each of the VBP tools utilized. Some of the measures may be overlapping.

ACS CAN urges CMS to identify the measures used through an open, public, and transparent process. Such measures should be developed through a multi-stakeholder entity like the NQF. Given the technical nature of quality measure development, we urge CMS to provide at least a 60-day comment period in which to respond and provide feedback to CMS' proposed quality measures. All comments received should be made publicly available so that stakeholders have an opportunity to review any and all comments and determine the extent to which consensus exists. Further, we strongly urge CMS to delay implementation of the Part B Drug Payment Model until it has finalized at least a preliminary set of quality measures that will be used to safeguard beneficiary access to Part B drugs.

Timeframe: ACS CAN is concerned the proposed implementation timeframe for Phase II fails to provide adequate opportunity for public comment before implementing the VBP tools proposed by CMS. We strongly urge CMS to delay any implementation of Phase II until it has had an opportunity to fully implement and conduct an initial evaluation of the first phase of the Part B Drug Payment Model to ensure that any beneficiary access problems and/or unintended consequences are addressed before moving to the next phase of the model.

Variation in the use of VBP tools: It is unclear from the preamble the extent to which CMS envisions the implementation of the VBP tools. While CMS has stated that a VBP tool will be applied to a specific HCPC code, it is unclear whether each geographic unit (i.e., PCSA as proposed in the rule) would be subject to all of the approved VBP tools or whether the contractor(s) responsible for implementing the VBP tools would be permitted to determine which VBP tool (if any) would be appropriate for a given geographic area.

Assuming CMS finalizes its policy of defining the geographic unit as a PCSA, there would presumably be approximately 3500 geographic units where VBP tools could be imposed. If CMS determines that a specific drug is appropriate for a specific VBP tool, it is unclear whether that tool will be uniformly applied to all geographic units implementing VBP tools (e.g., 3500 PCSAs) or whether each of the geographic units would have the opportunity to develop their own version of the specific VBP tool. We would caution against multiple versions of the same VBP tool being implemented in each geographic

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Part B Drug Payment Model, the Pew Charitable Trusts, Apr. 11, 2016, available at http://www.pewtrusts.org/en/about/events/2016/public-forum-on-the-medicare-part-b-drug-payment-model.

area. Such a policy would prove too onerous for adequate stakeholder involvement. Moreover, evaluation of the VBP tool would prove challenging if CMS were to attempt to evaluate similar versions of the same tool in different geographic areas.

Adherence: As CMS drafts its VBP tools, we urge CMS to clarify whether a provider who utilizes VBP tools must maintain a 100 percent adherence to these tools or whether the provider is permitted to prescribe outside the tools. Particularly in cancer care, it may be medically appropriate – depending upon the evidence and individual needs of the beneficiary – for the provider to deviate from the standard of care. It is for this reason that the American Society of Clinical Oncology recommends that clinical pathways do not seek a 100 percent adherence rate, but rather establish a more realistic adherence rate of 80 percent in order to allow providers the opportunity to prescribe according to the individual needs of the patient.[38]

3. Development of a Clinical Decision Support Tool

One component of value-based purchasing proposed by CMS is the development and use of clinical decision support (CDS) tools, for accurate clinical decision-making based on up-to-date scientific and medical evidence. In the preamble, CMS references specific examples of CDS tools including standardized drug and test orders that are developed from evidence-based medical guidelines when prescribing for a particular condition or type of patient; preventive care reminders; and alerts about potentially dangerous situations such as adverse drug events.[39] CMS proposes a two component CDS tool that consists of an online tool that supports clinical decisions through education and provides feedback based on drug utilization of Medicare claims.

CDS design: It is unclear from the preamble whether the CDS tools are intended to be text-based logic trees or whether CMS intends to incorporate specific software to be used by providers. If the latter, it is unclear whether CMS intends for the software to be a stand-alone system or whether CMS envisions the software to be based off the provider's existing claims and/or administrative software, as well as the extent to which the CDS tool will be integrated into electronic medical records. In order to be effectively utilized by providers, the CDS tools should be embedded into the electronic medical records. To the extent that CMS intends for this outcome, we encourage the agency to work with the National Institute of Standards and Technology (NIST) to develop pilot testing to ensure that the integration of the CDS tools work with the electronic medical records.

Process for developing the CDS: We appreciate CMS' recognition that clinical decision support tools can help providers choose the best treatment for the beneficiary. As noted in the preamble, the National Comprehensive Cancer Network (NCCN) publishes evidence-based clinical practice guidelines to assist oncologists in determining the most appropriate cancer treatment.[40]

We urge CMS to use existing evidence-based standards rather than creating new standards. We note that the Institute of Medicine has created requirements for the creation of high-quality guidelines[41] and

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[38] Zon RT, Frame JN, Neuss MN, Page RD, Wollins DS, Stranne S, Bosserman LD, American Society of Clinical Oncology Policy Statement on Clinical Pathways in Oncology, JOP Mar. 2016, vol. 12 no. 3. 261-266.

[39] 81 Fed. Reg. at 13245.

[40] More information on the NCCN guideline process is available at www.nccn.org.

[41] Graham R, Mancher M, Wolman DM, et al., Clinical Practice Guidelines We Can Trust, Institute of Medicine, National Academies Press, 2011.

we urge CMS to adhere to these standards. Given that in the oncology arena the NCCN guidelines are well regarded and utilized – in large part because they are developed through an evidence-based multi-stakeholder process – we urge CMS not to circumvent the NCCN process and create a separate clinical decision support tool to be used in oncology care. Rather, we urge CMS to incorporate the NCCN process into its clinical decision support tool with respect to oncology care.

CDS development feedback: The preamble notes that the CDS tool will be developed by CMS with support from the VBP contractor[42] and notes that CMS would consider feedback from the public on the evidence base for 30 days before finalizing a CDS tool for a specific indication.[43]

ACS CAN appreciates CMS' intention to "consider" feedback on the evidence that serves as the basis for the CDS prior to finalizing the CDS tool. However, we urge CMS to provide additional information regarding what constitutes consideration of feedback. We urge CMS to create an open and transparent process for solicitation of feedback both for the evidence being utilized in the development of the CDS, but also in the final CDS product. This process should include extensive opportunity for public feedback and public comments should be posted on the CMS website. Finally, we urge CMS to clarify its intent to test the CDS tool with providers prior to implementation to ensure the usefulness of the tool.

Treatment decision counseling: CDS tools should be developed and utilized with both patients and providers in mind. We are disappointed that CMS missed the opportunity to clarify that the CDS tool should be developed as a treatment decision counseling tool. While education of providers is an important aspect to improving the quality of health care, we caution that CDS tools should not be developed solely for the provider. Beneficiaries need to be informed of their treatment options and then be allowed to have meaningful conversations with their provider to discuss the benefits and risks of each treatment option. CMS should also consider developing CDS-like tools to educate the beneficiary (as the NCCN has done with its development of materials specifically geared toward patients and meant to facilitate informed provider-patient discussions). As CMS finalizes the rule we urge the agency to develop the CDS so that the patient is represented in the equation.

C. Comment Solicitation

1. Episode-Based or Bundled Pricing Approach: Solicitation of Public Comments

CMS is soliciting comments and suggestions to consider in future rulemaking related to an episode-based or bundled pricing approach for Part B drugs in both physician offices and hospital outpatient settings.

ACS CAN is supportive of the Oncology Care Model (OCM) currently being implemented by CMS. However, we note that the OCM begins at the point of administration of chemotherapy. While chemotherapy is often a major component of cancer treatment it is by no means the only form of treatment – surgery and radiation are other types of cancer treatment options. We would urge CMMI to consider the development of a future oncology model in which eligibility begins closer to the point of diagnosis and includes transitions back into primary care following the end of cancer treatment as appropriate. This will allow CMS the opportunity to evaluate all the factors that affect the course of cancer treatment to determine the extent to which the quality of cancer care can be improved through informed decision making.

[42] 81 Fed. Reg. at 13245.
[43] 81 Fed. Reg. at 13246.

D. Interactions With Other Payment Models

2. Most Shared Savings Programs and Models

CMS proposes not to exclude from the Part B Drug Payment Model beneficiaries assigned to an Accountable Care Organization (ACO) in the Medicare Shared Savings Program or otherwise accounted for in the shared savings model.

ASC CAN notes that the National Association of Quality Assurance (NCQA) is in the process of evaluating a patient-centered oncology care model, which has been shown to improve quality for beneficiaries and reduce health care expenditures.[44] This program is currently being expanded to be tested in additional sites across the country. Given the initial indications of the success of these programs, we urge CMS to consider exempting providers participating in the oncology Patient-Centered Medical Home (PCMH) from the Part B Drug Payment Model.

3. Oncology Care Model

CMS notes the overlap between the Part B Drug Payment Model and the Oncology Care Model (OCM) currently being tested by CMMI. However, CMS intends to include OCM practices in all arms of the Part B Drug Payment Model.

ACS CAN supports CMMI's Oncology Care Model which we believe has the potential to improve the quality of care for cancer patients actively undergoing chemotherapy treatments. We strongly urge CMS to exclude participants in the OCM from the Part B Drug Payment Model. We note that since the release of the proposed rule, representatives from CMS have been reported as being favorably inclined to this change.[45]

The OCM represents an opportunity to test a new delivery payment model for the administration of chemotherapy and supportive care for Medicare beneficiaries in active cancer treatment. In its original Request for Applications, CMS indicated that it expected to receive approximately 100 applications from providers to participate in this model,[46] which it believes would provide sufficient participation in which to effectively evaluate the model. We note that participation in the OCM model is voluntary for providers whereas participation in the Part B Drug Payment Model is not. Both models will result in varying degrees of change for a provider's practice. We are concerned that providers who may have intended to participate in the OCM model may withdraw from the OCM due to concern that participation in two unique payment models may prove too onerous for the provider's practice. As such, CMMI ultimately may not receive the minimum participation necessary in order to test and evaluate the OCM.

Thus, we strongly urge CMS to exempt from the Part B Drug Payment Model those practices who participate in the OCM. We believe this exemption will ensure a more accurate evaluation of the OCM model, and may result in additional provider interest in the OCM.

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[44] Sprandio J.D., Oncology Patient-Centered Medical Home, *J. Oncol. Prac.* 27 Feb. 2017.

[45] Wilkerson J, Two CMS Officials: CMS Eyes Excluding Oncology Care Model Practices from Part B Drug Demo, Inside Health Policy (Apr. 11. 2016).

[46] CMS Centers for Medicare & Medicaid Innovation, Oncology Care Model (OCM) Request for Applications (RFA), Feb. 2015, available at https://innovation.cms.gov/Files/x/ocmrfa.pdf.

IV. Provider, Supplier, and Beneficiary Protections

A. Pre-Appeals Payment Exceptions Review Process

CMS proposes to establish a Pre-Appeals Payment Exceptions Review process for pricing established under the value-based pricing section of Phase II in order to allow an opportunity to dispute payments made under Phase II. The proposed rule notes this new process would be in addition to – and not in lieu of – the current appeals process. This process only would be available to providers, suppliers, or beneficiaries receiving services in areas assigned to one or more of the VBP arms and would not include any modifications to the ASP add-on. The Pre-Appeals Payment Exceptions Review process would allow the provider, supplier, or beneficiary to contact the contractor prior to submitting a claim, and explain why the exception to the Medicare pricing policy is warranted. The contractor would provide a written decision within 5 business days of receipt of the exception. The Pre-Appeals Payment Exceptions Review process would not confer any appeals rights, though claimants would be permitted to file an appeal after the submission of a claim.

Beneficiary awareness: ACS CAN supports CMS' proposal to establish a new pre-appeals mechanism. We appreciate the proposed rule's clarification that this Pre-Appeals Payment Exceptions Review process will be in addition to – and not in lieu of – the existing Medicare appeals processes. However, we are concerned that as a practical matter, Medicare beneficiaries may not be made fully aware of these new pre-appeals rights. Historically very few Medicare appeals are filed by beneficiaries.[47] In addition, the Pre-Appeals Payment Exceptions Review process only would be available prior to the submission of a claim subject to VBP tools. Medicare beneficiaries often are unaware of the timing of a submission of a Medicare claim on their behalf and thus may miss out on the ability to take advantage of this additional pre-appeals process.

Beneficiaries who utilize their Medicare appeals rights are often told of their rights by their health care provider. To the extent that the provider has a financial incentive to utilize one treatment over another (e.g., due to reference pricing) then the provider would be less inclined to inform the beneficiary of her/his new pre-appeals rights. Therefore, we are concerned that appropriate pre-appeals will not be filed and some patients will not receive access to the treatments that are right for them.

Beneficiary cost-sharing: The preamble notes that "[t]hroughout this process, providers and suppliers would be prohibited from charging a beneficiary more than the applicable cost sharing [provided under the VBP tool] even if a payment exceptions request is not approved by the contractor or the payment amount determined by the contractor remains unchanged as a result of the appeals process."[48] We appreciate CMS' acknowledgement that the Pre-Appeals Payment Exceptions Review process cannot be used by a provider or supplier as a back-door way to impose higher cost-sharing on the beneficiary than would otherwise be required. We urge CMS to codify this important beneficiary protection into the final rule.

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[47] According to the HHS Office of Inspector General (OIG) five percent or less of the Medicare redeterminations (i.e., the first level of review) came from beneficiaries or their representatives. Department of Health and Human Services Office of Inspector General, The First Level of Medicare Appeals Process, 2008-2012: Volume, Outcomes, and Timelines, Oct. 2013, available at http://oig.hhs.gov/oei/reports/oei-01-12-00150.pdf.

[48] 81 Fed. Reg. at 13250.

In addition, it is not clear whether the Pre-Appeals Payment Exceptions Review process could result in a beneficiary incurring higher cost-sharing. Under the proposal, a supplier or physician could utilize the Pre-Appeals Payment Exceptions Review process to obtain a higher reimbursement. Beneficiaries without supplemental coverage pay 20 percent cost-sharing for Part B services. Thus, if a supplier's or physician's successful appeal resulted in a higher reimbursement, beneficiary cost-sharing would also increase.

This creates a number of potential problems. A beneficiary would likely be confused upon receiving a supplemental bill from her/his provider – presumably months after the service was provided – to account for the additional cost-sharing she/he would be required to pay as a result of the provider's successful appeal. In addition, the assessment of the additional cost-sharing would be conducted after the submission of the claim (and after the provider's successful appeal) and thus by definition the beneficiary would be unable to utilize the Pre-Appeals Payment Exceptions Review process. The beneficiary's only recourse would be the current review process, which could take significantly longer to adjudicate.

We strongly urge CMS to clarify that in cases where the provider's or supplier's appeal results in a higher reimbursement, the beneficiary should be held harmless to the original cost-sharing amount to which she/he was otherwise required to pay.

Expedited timeframe: The proposed rule requires the Payment Exceptions decision to be issued, in writing, within five business days of receipt of the request. ACS CAN supports CMS' policy that requires prompt review of Payment Exceptions. We urge CMS also to require an expedited appeals process in cases where the beneficiary or her/his physician believes that waiting for a decision under the standard time frame could place the beneficiary's life, health, or ability to regain maximum function in serious jeopardy.

Data collection: Given historically low beneficiary utilization of the Medicare appeals process, we strongly urge CMS to establish a process to use real-time data to actively monitor how beneficiaries utilize the Pre-Appeals Payment Exceptions Review process. This real-time information will help CMS identify the extent to which the use of the VBP tools in general and/or the use of a particular VBP tool may be hindering beneficiaries' access to Part B drugs. In the event that such access problems occur, it could be helpful to know whether the access problems are occurring in specific geographic areas, or with specific contractors, or whether the use of specific VBP tools are hindering access.

As discussed in more detail below, we urge CMS to make clear that it intends to use real-time data on the use of beneficiary appeals under the Pre-Appeals Payment Exceptions Review process as one of many tools to evaluate the Part B Drug Payment Model. When promulgating the final rule, CMS should codify its ability to be able to halt the use of one or more VBP tools – on a temporary or permanent basis and regionally or nationally – if it is determined in part through the real-time monitoring of beneficiaries' use of the Pre-Appeals Payment Exceptions Review process that beneficiary access is hindered by the use of the tool(s).

VI. Evaluation

CMS proposes to evaluate the Part B Drug Payment Model similar to other models developed and tested under CMMI's authority. The preamble notes that CMS "will compare historic patterns of Part B drug use and Medicare program costs for providers and suppliers, and health outcomes for beneficiaries in response to the alternative interventions proposed in the [Part B Drug Payment Model]."[49]

ACS CAN is deeply concerned that the proposed rule focuses more on the potential for cost savings and provides little specific information (other than a few notable exceptions discussed in greater detail below) regarding how CMS intends to ensure the quality of care for Medicare beneficiaries is preserved or enhanced. Improving quality should be one of the basic outcomes of a CMMI demonstration. In fact, the CMMI was created to "test innovative payment and service delivery models to reduce program expenditures … while preserving or enhancing the quality of care furnished to individuals"[50] who receive Medicare, Medicaid, or Children's Health Insurance benefits. We believe improved quality for the patient is as important as program savings. Therefore, we urge CMS to clarify how it will ensure that the quality of care provided to beneficiaries is maintained or improved under the Part B Drug Payment Model.

Beneficiary evaluation: ACS CAN is pleased with CMS' intent to include beneficiaries in its evaluation of the Part B Drug Payment Model. As discussed in more detail above, we are concerned that some of the proposed policies could hinder beneficiary access to medically necessary treatments and thus urge CMS to develop a specific set of evaluation tools that would allow access to real-time data to ensure that beneficiaries do not experience access problems. We understand that CMS has access to claims data on an almost real-time basis – with as little as two- or three-day lag time.[51] We urge CMS to utilize this real-time data to ensure beneficiary access is protected.

The preamble states that CMS "may consider a survey of beneficiaries, suppliers, and providers to provide insights on beneficiaries' experience under the model and additional information on any strategies undertaken by those providing drugs included under this model."[52] We strongly urge CMS to conduct this beneficiary survey – including focus groups from beneficiaries who are taking one or more of the top 10 drugs where 50 percent of the payment reductions are expected to result. In 2014, more than 1 million Medicare beneficiaries were treated with one of these 10 drugs.[53] We agree with CMS that it is important to include providers and suppliers in its evaluation of the impact of the model on beneficiaries. However, we caution CMS that these stakeholders' views should not be used as a surrogate for the views of actual beneficiaries who have participated in the Part B Drug Payment Model.

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[49] 81 Fed. Reg. at 13252.

[50] 42 U.S.C. § 1315a(a)(1).

[51] Remarks from Dr. Patrick Conway, Acting Principal Deputy Administrator, Deputy Administrator for Innovation and Quality, and Chief Medical Officer, Centers for Medicare and Medicaid Services, Public Forum on the Medicare Part B Drug Payment Model, the Pew Charitable Trusts, Apr. 11, 2016, available at http://www.pewtrusts.org/en/about/events/2016/public-forum-on-the-medicare-part-b-drug-payment-model.

[52] 81 Fed. Reg. at 13252 (emphasis added).

[53] Fauzea Hussain and Adam Borden, "Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers," Avalere: Washington, D.C. (April 7, 2016), available at http://avalere.com/expertise/managed-care/insights/proposed-medicare-part-b-rule-would-reduce-payments-to-hospitals-and-some-s.

Specific oncology evaluation: Oncology drugs represent 42 percent of Part B spending,[54] and according to one analysis more than 50 percent of the payment reductions that would result from the proposed methodology change come from 10 drugs, seven of which are oncology drugs.[55] As discussed in more detail above, we are concerned about the potential impact of the Part B Drug Payment Model on beneficiaries with cancer. Thus, we urge CMS in its evaluation to conduct specific analysis regarding beneficiary access to oncology care. Included in this analysis must be a determination of the extent to which the Part B Drug Payment Model has resulted in disruptions in beneficiary care and beneficiaries having to get care in higher-cost sites.

Additional beneficiary safeguards: As discussed in more detail above, ACS CAN is deeply concerned that the proposed Part B Drug Payment Model could hinder beneficiary access to medically necessary cancer treatments. We note that CMS has indicated it has the ability to be able to access in real time claims data to evaluate a new payment model.[56] We strongly urge CMS to engage this evaluation tool to ensure that beneficiaries' access to oncology medications is not hindered – including monitoring the extent to which beneficiaries are accessing oncology services through a higher cost site of care. Prior to the launch of any new payment model CMS should develop a contingency plan to be triggered in the event that the real-time evaluation reveals beneficiary access problems. Such a plan must clearly identify the action steps CMS will implement in the event that access problems are identified. We strongly urge CMS to develop this plan and solicit stakeholder comments through an open and transparent comment process.

Periodic evaluations: As part of its evaluation process, we urge CMS to conduct evaluations of the Part B Drug Payment Model on a yearly basis. The results of these evaluations should be made publicly available shortly after their completion so that interested parties can obtain a better understanding of any concerns or problems that may arise. Releasing an evaluation at the conclusion of the Model – particularly given the Model's five-year scope – would be too long of a delay.

Quality measures: We are pleased the preamble references the fact that CMS intends to evaluate the quality of care provided under the Part B Drug Payment Model. However, the preamble is silent with respect to which specific quality measures CMS is considering as requirements in the model. As discussed in more detail above, we urge CMS to adopt quality measures that have been accredited by a multi-stakeholder entity through an evidence-based process and should include patient experience measures.

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[54] HHS Office of the Assistant Secretary for Planning and Evaluation, Medicare Part B Drugs: Pricing and Incentives, March 8, 2016, available at https://aspe.hhs.gov/sites/default/files/pdf/187581/PartBDrug.pdf.

[55] Fauzea Hussain and Adam Borden, "Proposed Medicare Part B Rule Would Reduce Payments to Hospitals and Some Specialists, While Increasing Payments to Primary Care Providers," Avalere: Washington, D.C. (April 7, 2016), available at http://avalere.com/expertise/managed-care/insights/proposed-medicare-part-b-rule-would-reduce-payments-to-hospitals-and-some-s.

[56] Remarks from Dr. Patrick Conway, Acting Principal Deputy Administrator, Deputy Administrator for Innovation and Quality, and Chief Medical Officer, Centers for Medicare and Medicaid Services, Public Forum on the Medicare Part B Drug Payment Model, the Pew Charitable Trusts, Apr. 11, 2016, available at http://www.pewtrusts.org/en/about/events/2016/public-forum-on-the-medicare-part-b-drug-payment-model.

In order to be effective, any quality measures must be identified and available for at least a 45-day public comment period before CMS finalizes the use of the measures. This process will allow for sufficient time for stakeholders to provide input on the number and specific measures being proposed by CMS.

In addition, given that the Part B Drug Payment Model is intended to be five years in scope, we urge CMS to include some quality measures that are intended to remain in place throughout the duration of the model. However, we also anticipate that CMS will add new quality measures to the model as well.

CMS intimated that some of the quality measures that will be included in the Part B Drug Payment Model will be patient-reported outcome measures (PROMs).[57] ACS CAN is pleased that CMS is considering adding PROMs to the quality measures that will be used to evaluate this new model. We note that in cancer care, beneficiaries may choose a treatment option based on a variety of factors – the drug's toxicity, side-effects, interaction with other drugs, etc. Many of these factors differ among patients. As CMS begins the process of developing PROMs, we urge the agency to specifically develop PROMs for cancer patients.

Simultaneous MACRA implementation: CMS proposes simultaneous implementation of physician reimbursement changes imposed under MACRA and the Part B Drug Payment Model. We are concerned that the simultaneous implementation of two major changes to Part B reimbursement for physicians may make it harder for CMS to evaluate the Part B Drug Payment Model. Thus, as discussed in more detail above, we strongly urge CMS to reconsider implementing the model on a national scope, and rather identify a number of smaller, targeted geographic areas in which to test the model.

Conclusion

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the Medicare Part B Drug Payment Model proposed rule. As discussed in more detail above, ACS CAN is deeply concerned with the Medicare Part B Drug Payment Model as proposed by CMS, and we urge CMS to address these concerns before implementing any new Part B payment policies. ACS CAN is concerned the proposal has the potential to result in beneficiaries being unable to access their cancer medications in the setting of care that is right for them. We note that one unintended consequence of the Part B Drug Payment Model will likely be a shift in some care to higher-cost settings. Unfortunately, if providers are unable or unwilling to dispense a medically necessary Part B drug due to the reimbursement rate, beneficiaries who need that treatment may have no choice but to seek care in a higher-cost setting. This result would be particularly problematic for beneficiaries who reside in rural areas who have fewer treatment options and who may be forced to travel further distances to receive care. As CMS considers implementing the VBP tools, we urge the agency to balance the impact of the tools with advancements in treatments based on personalized medicine, including treatments based on genetic information, and issues related to side-effects and drug-to-drug interactions.

[57] Id.

ACS CAN is pleased the proposed rule recognizes that clinical decision support tools can help providers choose the best treatment for the beneficiary. CDS tools should be developed and utilized with both patients and providers in mind. We are disappointed that CMS missed the opportunity to clarify that the CDS tool should be developed as a treatment decision counseling tool so that a patient and his/her provider can work together to determine the best course of treatment based on the individual preferences of the patient. Similarly, while we are pleased that CMS established the Pre-Appeals Payment Exceptions Review Process as part of the Part B Drug Payment Model, we note that beneficiaries typically do not take advantage of their appeals rights and often are only informed of their rights by their provider. We strongly urge CMS to clarify policies to ensure that this process will not result in beneficiaries being charged higher cost-sharing.

Finally, we urge CMS in its evaluation to conduct specific analyses regarding beneficiary access to oncology care. Included in this analysis should be a determination of the extent to which the Part B Drug Payment Model has resulted in disruptions in beneficiary care and beneficiaries having to get care in higher cost sites of care. We urge CMS to provide additional information regarding the specific quality measures it intends to use to evaluate this model and encourage the adoption of outcomes measures over process measures.

Ultimately, this proposed rule is a long way from where it needs to be and could well create significant harm as currently drafted. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org or 202-585-3261.

Sincerely,

Christopher W. Hansen
President
American Cancer Society Cancer Action Network