May 9, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

BY ELECTRONIC DELIVERY

Re: Medicare Program; Part B Drug Payment Model; Proposed Rule (CMS-1670-P)

Dear Administrator Slavitt:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Part B Drug Payment Model (Model) Proposed Rule (the "Proposed Rule"), published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on March 11, 2016.[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, pharmacists, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 20,000 cancer care professionals from approximately 2,000 hospitals and private practices nationwide. It is estimated that 65 percent of cancer patients nationwide are treated by a member of ACCC.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to appropriate cancer therapies in the most appropriate setting. The cancer care delivery infrastructure is a fragile construct of hospital outpatient departments and physician offices working together to provide care to patients in their communities. Physicians and providers face growing numbers of patients requiring cancer care, and their ability to provide care will depend on appropriate Medicare payment rates for cancer care, including drugs and other services.

[1] 81 Fed. Reg. 13,230 (March 11, 2016).

The health care payment and delivery paradigm in the United States is increasingly shifting to value-based care system, and community cancer centers are part of this reform effort. We fully support the overarching goal of this shift to bend the cost curve by improving care, providing the right care at the right time, reducing over-treatment and under-treatment, and reducing hospital admissions and readmissions. ACCC members have a long history of partnering with CMS on meaningful payment reform including, most recently, the Oncology Care Model (OCM). We also will be dedicating significant resources to navigating the new physician payment reforms under the Medicare Access and Chip Reauthorization Act (MACRA) of 2015.

ACCC and its members generally recognize the need for a broad, national conversation about pharmaceutical pricing and to identifying solutions for reining in drug costs for the Medicare program and beneficiaries, but we also believe this conversation needs to consider the costs and benefits of all aspects of quality cancer care, not just drug costs. The proposed Model is narrowly focused on drug cost alone, without considering the full array of items and services needed to treat cancer patients, and without recognizing that the providers whose reimbursement would be cut under the Model have no control over drug prices. As we discuss in more detail below, cancer care providers already are being challenged to provide care at reduced payment rates because of sequestration. In fact, for many hospitals, these rates currently are less than acquisition cost for numerous anti-cancer drugs. Further reductions in reimbursement are simply not justified and may not be sustainable.

In addition, unlike the OCM and the physician payment reforms under MACRA, the Model has been proposed for quick implementation with little opportunity for input from stakeholders before CMS released the Proposed Rule. We believe further discussion with providers and other stakeholders is needed to refine the Model to ensure that it truly creates incentives for providing high quality care and includes essential protections against underutilization of drugs and other elements of cancer care. A more deliberative approach also would help to ensure that any payment changes can be implemented without disruptions to care while physicians adapt MACRA reforms and providers adjust to the new costly and cumbersome United States Pharmacopeia (USP) 800 standards.

ACCC urges CMS to withdraw the proposal in its entirety and to engage instead with stakeholders in a thoughtful, data-driven conversation about drug pricing and prudent strategies to optimize use of resources for cancer treatment. Specifically, ACCC recommends that CMS withdraw the Model for the following reasons:

- The Model is based on a deeply flawed rationale;
- The proposed reimbursement for Part B drugs at average sales price (ASP) plus 2.5 percent plus $16.80 per drug per day would be less than the acquisition cost for many Part B drugs for many providers, for whom reimbursement after sequestration is already below cost;
- The Model would leave unchanged CMS's packaging policies under the Hospital Outpatient Prospective Payment System (OPPS) and fails to assess how these policies would interact with the proposed payment reforms;

- CMS has not appropriately assessed the impact of overlaying the Model on top of other demonstration programs such as the Oncology Care Model (OCM);
- Phase II of the Model involves complex assessments of value and clinical comparisons that require much more public discussion;
- The Model lacks essential patient protections; and
- The Model's scope and timeline are too ambitious for providers and CMS to implement effectively.

1. The Model is based on a deeply flawed rationale.

We are deeply troubled by CMS's flawed rationale for the proposed Model and its failure to include necessary patient protections. CMS explains that the proposed Model, which would increase reimbursement for lower cost therapies and reduce reimbursement for all therapies costing more than $480 per day, seeks to "remove any excess financial incentive to prescribe high cost drugs over lower cost ones when comparable low cost drugs are available."[2] This statement is based on two faulty assumptions: (1) providers currently have "excess financial incentives" to prescribe high cost drugs; and (2) all therapies have lower cost comparable options.

First, our members strive to provide the best care possible to their patients, including the most appropriate drug therapies, with the choice of treatment being guided by clinical evidence and the patient's needs, not economics. It may be inevitable that financial considerations will come into play in some patients' care, particularly as patients increasingly struggle with cost-sharing obligations. However, our members' goal is to provide the best quality care, regardless of cost. Any model that seeks to change the cost of care without also providing protections for the quality of care is inherently flawed.

Second, CMS assumes that there will be "comparable low cost drugs" for most patients. In reality, in many cases, there may be only one appropriate drug for a patient with a specific type and stage of cancer. For example, there are no viable alternatives for therapies such as trastuzumab for human epidermal growth factor receptor 2 (HER2) positive breast cancer, rituximab for many lymphomas, and bortezomib for most patients with multiple myeloma. In other cases, where there are alternatives, those alternatives present significant adverse side effects to patients. Physicians may need to choose between pemetrexed and paclitaxel to lessen peripheral neuropathy or between bendamustine and CHOP (Cyclophosphamide, Hydroxydaunorubicin, Oncovin and Prednisone or Prednisolone) to avoid cardiac toxicity. Medicare's reimbursement methods should not be based on an inaccurate assumption that providers have multiple drugs to choose from for each patient or penalize providers for selecting the most appropriate therapy for the patient – a choice that requires more complex considerations than simply cost, including toxicities and individual patient needs and preferences. This is particularly important for Medicare patients, who are often the oldest, sickest patients and need access to multiple drugs. Instead, the proposed Model would amount to taking personalized medicine and putting it secondary to economics.

[2] *Id.* at 13,233.

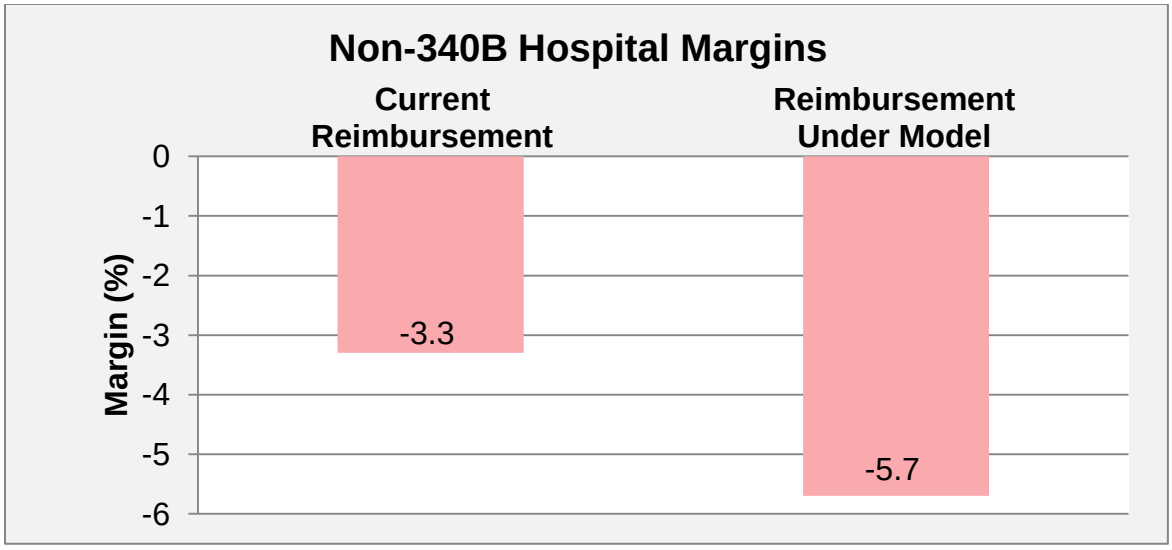
2. The proposed reimbursement for Part B drugs at ASP plus 2.5 percent plus $16.80 per drug per day would be less than the acquisition cost for many Part B drugs for many providers, for whom reimbursement after sequestration is already below cost.

ACCC is very concerned that CMS has not fully considered the implications of this proposal for oncology providers and beneficiaries who depend on access to life-saving Part B medicines in their fight against cancer. Maintaining appropriate reimbursement rates for cancer drugs is critical to protecting the health of patients who need them. Under Phase I of the Model, the payment rate for all included Part B drugs and biologicals in half of the country would be changed from ASP plus 6 percent to ASP plus 2.5 percent and a $16.80 flat fee per administration per day, prior to application of sequestration. Accounting for mandatory reduction in Medicare's share of payment by two percent due to sequestration, the current payment rate for Part B drugs is effectively ASP plus 4.3 percent, and the proposed rate under Phase I of the Model, the effective payment rate accounting for sequestration would be reduced to ASP plus 0.86 percent and a $16.53 flat fee per drug per day.

ASP is an average; providers acquire Part B drugs at varied prices. In addition, hospitals and physician offices acquire various drugs at different prices relative to ASP. Some purchasers are less able to obtain discounts, and acquisition prices for a particular provider can vary from less than ASP to considerably more than ASP. Hospitals and physicians also typically do not receive the prompt pay discounts that are provided to wholesalers and are factored into the calculation of ASP. In addition, hospitals and physicians incur other costs associated with providing drugs to patients, including the costs of safely storing, preparing, and disposing of drugs, and compliance with pharmacy standards such as the new USP 800 standards. The current reimbursement method of ASP plus 6 percent helps to ensure that Medicare payment is more than the costs of acquiring drugs and providing related pharmacy services.

To understand the potential effect of the Model's proposed reimbursement changes on providers of cancer care, ACCC commissioned a study by Pharmacy Consulting International (PCI) of acquisition cost compared to current and proposed reimbursement rates at a sample of hospitals. This analysis examined a snapshot of data from a sample of 24 hospitals located throughout the United States, including six non-340B -eligible hospitals, 11 340B-eligible disproportionate share (DSH) facilities, and seven 340B-eligible non-DSH facilities. This analysis found that the proposed reimbursement under the Model would have a significant adverse financial impact on hospital based outpatient departments for all categories of hospitals. The Model's impact would be particularly acute for the non-340B facilities in the sample. These hospitals currently are operating at a mean annualized gross margin of -3.3% on Part B drugs. Under the proposed reimbursement model, the mean annualized margin would fall to -5.7%,[3] meaning that these hospitals that already are losing money on Part B drugs, would face even greater losses under the Model. PCI concludes that these reductions in revenue "may adversely impact the sustainability of oncology programs at these hospitals."[4]

[3] Pharmacy Consulting International, Impact Analysis of Proposed CMS Reimbursement Model, (May 2016), at 1-2 (hereinafter "PCI Analysis").
[4] PCI Analysis at 7.



In addition, PCI assessed the current and proposed margins on the top 25 oncology drugs at each category of hospital in its sample and found that the model would have a disproportionately negative impact on oncology drugs. PCI found that non-340B hospitals currently have acquisition costs that exceed Medicare reimbursement for 15 of these drugs under the current methodology, and this number would increase to 19 under the proposed Model.[5] The change in margin for oncology drugs by type of facility in our sample would range from -7.1% at 340B DSH hospitals to -113.2% at non-340B hospitals. In comparison, the change in margin for non-oncology drugs ranges from -3.8% at 340B DSH and non-DSH hospitals to -19.0% at non-340B hospitals.

% Change in Margin by Hospital Type and Drug Category

	Non-Oncology Drugs	Oncology Related Drugs	All Drugs
Non-340B	**-19.0%**	**-113.2%**	**-67.8%**
340B DSH	**-3.8%**	**-7.1%**	**-5.1%**
340B Non-DSH	**-3.8%**	**-12.8%**	**-10.3%**

These hospitals have continued to provide high-quality cancer care to Medicare beneficiaries in the face of falling reimbursement and rising demand, but we are deeply concerned that their efforts will not be sustainable if the Model is implemented. As oncologists send more patients to hospitals for care, hospitals have taken on growing patient demand, particularly for higher cost therapies that physicians are unable to provide at Medicare's reimbursement rates. In a recent

[5] *Id.* at 12.

survey of oncologists, 80 percent said that sequestration cuts affected their practices and 50 percent are sending their patients elsewhere for chemotherapy.[6] A 2016 study by Milliman found that the proportion of chemotherapy infusions delivered in the hospital outpatient departments nearly tripled from 2004-2014, increasing from 15.85 to 45.9 percent in the Medicare population.[7] Our members are committed to serving all patients who need care, but we ask CMS to recognize that this is increasingly challenging as reimbursement rates drop, and would be even more difficult if the Model were implemented.

3. The Model would leave unchanged CMS's packaging policies under the OPPS and fails to assess how these policies would interact with the proposed payment reforms.

Moreover, although CMS describes Phase I of the Model as having the "overall effect of modestly shifting money from hospitals and specialties that use higher cost drugs, such as ophthalmology, to specialties that use lower cost drugs, including primary care, pain management, and orthopedic specialties,"[8] hospitals would not experience the full benefits of this shift due to CMS's packaging policies under the OPPS. Many lower cost drugs are not separately reimbursed in the OPPS, and CMS proposes not to provide the $16.80 per drug per day payment ($16.53 after sequestration) to these drugs.[9] If these drugs had been separately reimbursed in the hospital outpatient setting, as they are in the physician office setting, the hospitals in PCI's sample would receive an additional $27 million in reimbursement.[10] This additional reimbursement would help to offset the payment cuts for higher-cost therapies, but is not being offered to hospitals.

As a result, the Model is deeply flawed because it would not offer uniform incentives across providers. By continuing to apply CMS's packaging policies under the Model, CMS does not propose a level playing field for hospitals and physician offices. Before moving forward with any changes in reimbursement, we urge CMS to closely analyze the interaction of its packaging policies with proposed payment changes and to present that analysis to stakeholders for public comment. For years, ACCC has urged CMS to pay separately for each drug with a Healthcare Common Procedural Coding System (HCPCS) code in the OPPS just as it does in the physician office setting. We ask CMS to reassess this decision once again when it analyzes this issue in conjunction with the Model.

[6] American Society of Clinical Oncology. ASCO Sequestration Impact Survey: One Month Out, Sequestration Affecting Care of Medicare Cancer Patients. http://www.asco.org/advocacy/asco-sequestration-impact-survey-one-month-out-sequestration-affecting-care-medicare-cancer, May 10, 2013.
[7] Milliman study Commissioned by COA. "Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014."
[8] 81 Fed. Reg. at 13,233.
[9] *Id.* at 13,259.
[10] PCI Analysis at 2.

4. CMS has not appropriately assessed the impact of overlaying the Model on top of other demonstration programs such as the OCM.

CMS proposes to include practices participating in the OCM and other demonstration programs in the Model. CMS also specifically requests comment on the best approach for handling such overlap and whether OCM practices and their comparison practices should be excluded from the Model.[11]

ACCC urges CMS to exclude OCM participants from the Model to ensure that these participants are treated fairly and to protect the methodological soundness of the Model. When our members elected to participate in the OCM, their decisions and the corresponding underlying, complex financial analyses they performed were based on the expectation of reimbursement at ASP plus 6 percent. Overlaying the Model on top of the OCM effectively penalizes these providers by fundamentally changing the terms of the OCM that they evaluated and agreed to when they applied to participate. Practically speaking, many of our members will not be able to comply with extensive OCM infrastructure investments without the reimbursement rate they had assumed going into the model.

From a methodological perspective, the proposed stratified randomization by primary care service area (PCSA) does not account for participation in the OCM. As a result, OCM participants may not be evenly distributed across PCSAs, distorting any meaningful evaluation of potentially both the Model and the OCM. CMS should explicitly address how the baseline will be established for participants in the OCM and, under no circumstances, should CMS compare sites participating in both demonstrations to sites in the control arm of the Part B Drug Payment Model.

Although we believe it is logical to exclude OCM participants from the Model, if CMS chooses to include these providers in the Model, it should do so in a way that does not penalize them. As proposed, the Model fails to achieve this. Excluding OCM participants not only would preserve the methodological integrity of CMS' Model, but it would also exclude a very small number of providers from the Model: OCM participants only represent 10 percent to 15 percent of oncologists nationwide. We also recommend that CMS consider keeping the OCM open and allowing additional providers to join in subsequent rounds. ACCC strongly believes that the OCM is better suited to improve cancer care and contain costs than the Model as it integrates drug costs with other costs of treatment and attempts to decrease costly emergency room visits and inpatient admissions through more coordinated, round-the-clock care.

5. Phase II of the Model involves complex assessments of value and clinical comparisons that require much more public discussion.

Phase II of the Model involves development and implementation of value-based purchasing (VBP) tools, including reference pricing, indication-based pricing, outcomes-based risk sharing,

[11] 81 Fed. Reg. at 13,233.

and discounting or eliminating beneficiary coinsurance.[12] Inherent in these tools are complex assessments of value and comparisons of clinical effectiveness. These analyses are controversial and tools based on them should not be implemented without extensive discussion with stakeholders and additional opportunities for formal public comment.

ACCC and its members are concerned with the narrow definition of value that CMS espouses in the Model. Value should be assessed based on the benefits the medicine provides to the patient, the benefit it provides to society, and the extent to which the medicine has the benefit of advancing medical progress in a certain disease. We cannot agree with CMS's statement that the Proposed Model "will further our goals of smarter, that is, more efficient spending on quality care for Medicare beneficiaries"[13] unless the Model uses a definition of "value" that considers all of these factors. The centralized value assessment approach that CMS proposes with these VBP arrangements does not appropriately account for value from an individual patient perspective, which could lead to changes in reimbursement rates that discourage use of appropriate therapies. For example, CMS's proposed VBP tools in Phase II do not assess value in a patient-centric way. Instead, CMS proposes to base the determination of "value" on an average across to all patients by assessing, for example, "effectiveness" in very broad terms. This strategy encourages providers to apply broad "value" determinations across their entire patient population, regardless of the particular clinical circumstances of an individual patient.

We also are concerned about the proposed use of published studies produced by the Institute for Clinical and Economic Review (ICER) to determine clinical effectiveness of drugs.[14] ICER's value framework is proving to have significant flaws in implementation, including its lack of transparency and multi-stakeholder perspectives and its inability to provide meaningful direction on what constitutes value versus simply focusing on direct budget impact. Its analyses generally have been over-simplified and assume that the same general type of analysis and valuation can be applied uniformly to every drug and disease, ignoring critical differences among patient populations and therapies. ACCC is concerned that CMS identified ICER as a potential source of such information in light of these significant limitations in its research. ACCC encourages CMS, to the extent any such proposal is finalized, to more broadly identify potential third party sources for comparative clinical effectiveness data. For example, in the oncology community, sources such as the National Comprehensive Cancer Network (NCCN) guidelines represent a vetted and well-respected third party-resource.

6. The Model lacks essential patient protections.

Although the Model clearly is intended to change prescribing practices, the Model's only proposed patient protection measures, the Pre-Appeals Payment Exception Review (PAPER) Process, apply only to certain VBP tools in Phase II only.[15] Beneficiaries who are concerned about access to appropriate drugs in Phase I have no new patient protections and would have to turn to an already overburdened appeals process after a claim has been processed. CMS also

[12] 81 Fed. Reg. at 13,260.
[13] *Id.* at 13,230.
[14] *Id.* at 13,423, n. 23.
[15] *Id*. at 13,250.

does not propose any specific quality measures to ensure that patients continue to receive high-quality care under the Model. We urge CMS not to move forward with the Model until it develops and proposes robust patient protections.

7. The Model's scope and timeline are too ambitious for providers and CMS to implement effectively.

Cancer care providers are open to payment reforms that encourage higher quality care at lower cost, but for all of the reasons discussed above, we believe strongly that CMS's Model requires much more analysis and discussion to ensure that it achieves these goals. Unlike the OCM that ACCC strongly supports, this proposal was developed too quickly and with no input from stakeholders prior to release of the Proposed Rule. We urge CMS to withdraw the proposal and allow more time for thoughtful, data-driven conversations about both phases of the Model.

The Model represents a significant change to the current reimbursement methodology for Part B drugs. CMS therefore should allow sufficient time for stakeholders to make appropriate preparations. To this end, CMS' proposed target date of August 1, 2016, is overly ambitious, unrealistic, and too soon to permit stakeholders to prepare for changes in reimbursement. ACCC also found it very changing to produce a meaningful financial impact analysis of such a sweeping change in Part B reimbursement in such a short timeframe. Furthermore, the proposed timeline does not allow, practically speaking, for meaningful consideration of stakeholder comments. According to CMS's proposal, there is a minimum 60-day implementation period from publication of the final rule to implementation, comments are due on May 9, 2016, and CMS's target implementation date is August 1, 2016. Based on this schedule, CMS will have less than one month to consider and respond to stakeholder comments. This extremely brief timeline precludes meaningful consideration of stakeholder comments.

Given ACCC's long history of working with CMS on innovative proposals, ACCC knows that CMS values the opportunity to receive and respond to meaningful comments. The Model does not provide sufficient detail and specifics regarding the development and implementation of Phase II on which the public may provide comment. Additionally, CMS proposes to offer a short 30-day public comment period on the particular VBP tools and the specific codes that would be subject to each tool.[16] This timeline is inadequate given the complexity of issues posed and the dramatic impact on patient care that Phase II may have. To the extent that Phase II is finalized, ACCC strongly urges CMS to engage in formal rulemaking before mandating that any product or code be subjected to a particular VBP pricing approach.

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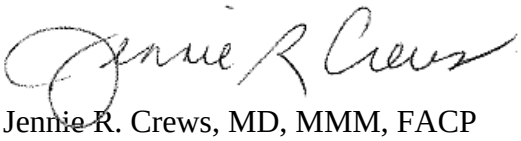
Thank you for this opportunity to comment on the Model. ACCC encourages CMS to carefully consider these comments and withdraw the Model in its entirety to protect Medicare beneficiaries nationwide. We look forward to continuing to work with CMS to address these

[16] *Id.* at 13,260.

critical issues in the future. Please feel free to contact Leah Ralph, Manager, Director of Health Policy, at (301) 984-5071 if you have any questions or need any additional information. Thank you again for your attention to these very important matters.

Respectfully submitted,



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