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September 15, 2015

Sheila Hanley
Director, Policy and Programs Group
Center for Medicare & Medicaid Innovation

VIA ELECTRONIC SUBMISSION TO:
HealthPlanInnovation@cms.hhs.gov

Re: Comments on Announcement of Medicare Advantage Value-Based Insurance Design Model Test

Dear Ms. Hanley,

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide feedback to the Center for Medicare & Medicaid Innovation (CMMI) on its Announcement of Medicare Advantage Value-Based Insurance Design (VBID) Model Test. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

Testing VBID in Medicare Advantage is a positive example of opportunities to ensure health care financing and delivery are supporting value in health care and recognizing the value of new medicines. By developing an initial demonstration with a well-defined scope, and examining opportunities focused on services, providers, disease management or other program participation, and additional supplemental benefits, CMMI is exploring a range of opportunities for VBID to increase the quality of care and reduce cost-sharing or provide additional benefits for targeted enrollees. We particularly appreciate that CMMI is seeking public input prior to the release of an RFA for this demonstration.

As the demonstration moves forward, it will be important to ensure that plans' VBID designs fully recognize the value of new medicines, support patient access to items and services that meet their individual needs, and preserve Part D's successful competitive structure and bidding process. Below are several principles we urge CMMI to consider as it further develops, implements and evaluates this model to ensure that VBID facilitates access to the full range of high-value care:

- VBID may be used by competing private plans as an alternative to blunt utilization management tools, such as high formulary tier placement and high cost-sharing based solely on price rather than value.
- VBID cost-sharing must be based on an appropriate assessment of value, not price.
- Value assessments should be based on the full body of available evidence, based on a range of study designs.
- Value must incorporate relevant clinical quality and patient-centered measures and account for changes in evidence, medical practice, and innovations.

- VBID should not lead to cost sharing increases for other covered items or services or reductions in the number of medicines on a health plan's formulary.
- VBID should not discourage enrollment of higher cost beneficiaries.

Below are specific recommendations about aspects of the model design.

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Model Waivers

Based on the preliminary guidance set forth in the September memorandum announcement, it appears CMMI has generally identified the waivers that may be appropriate for the Phase I model. However, we would also encourage CMMI to examine (and explain to stakeholders) whether it may be necessary to waive compliance with relevant program guidance, in particular the provisions on "Stratified co-payments for DME and/or Part B Drugs" and "Tiered cost-sharing of medical benefits" in Chapter 4 of the Medicare Managed Care Manual (MMCM),[1] as these provisions may limit an MA plan's ability to adopt a value-based design for Part B drugs.

This MMCM guidance permits tiered cost-sharing that meets certain standards for "contracted providers as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality."[2] Therefore, on its face, the guidance appears to allow tiered cost-sharing only for providers, and not for Part B drugs. The guidance does state that plans may use

> a stratified co-payment arrangement for DME and/or Part B drugs provided that: (1) for each strata, the co-payment amount is no greater than the CMS coinsurance requirement [i.e., 20%] for the lower limit of the strata, and (2) the number of co-payment strata does not exceed four.[3]

However, this "stratified" copay structure would not always accommodate VBID, because the various strata include all the drugs within a specified cost range, and stratification would thus require that two drugs with the same cost have the same copay, even if only one were considered high-value. For example, it appears that MA plans would be prohibited from reducing cost-sharing to $0 for diabetes drugs to promote compliance with treatment regimens (which is a classic example of VBID) unless all of the other diabetes drugs fell into the same cost range and all drugs within that cost range (for any indication) had their copay reduced to zero. It is unclear from this MMCM guidance whether it permits any type of tiered cost-sharing for Part B drugs other than this limited stratification, and therefore, could constrain the VBID model.

[1] MMCM Chap. 4 § 50.1.1.
[2] MMCM Chap. 4 § 50.1.1 (emphasis added).
[3] MMCM Chap. 4 § 50.1.1. This provision also includes an example of how stratification would work, i.e., drugs with a cost of $0-199 would have a zero copay; drugs with a cost of $200-499 would have a $40 copay; drugs with a cost of $500-999 would have a $100 copay; and drugs with a cost of 1000 and above would have a $200 copay.

Accordingly, we hope CMMI will address whether this MCCM guidance could conflict with VBID principles in connection with Part B drugs and (if so) whether a waiver may be appropriate. It may be that this provision does not need to be waived (either because the provision should be interpreted as giving MA plans more flexibility than it appears to with respect to cost-sharing for Part B drugs, or because CMMI does not believe it is necessary to grant waivers in order to authorize departures from sub-regulatory guidance), but CMMI has not addressed either of these issues at this juncture, so it is unclear whether the guidance could rule out certain VBID models.

PhRMA also appreciates CMMI identifying and seeking stakeholder input on the waivers it anticipates in connection with the Phase I VBID model before it grants any waivers and proceeds with testing the Phase I model. We urge CMMI to continue to be transparent if it later identifies additional waivers it anticipates granting. As we have noted in previous comments, we also recommend that -- for all Phase I models -- CMMI should document what waivers ultimately are granted, and should make that information publicly available in an easily-accessible location and format. We are not aware of any existing CMMI repository of information on what waivers CMMI has granted for each Phase I model, making it difficult for all stakeholders, not just participants, to understand and provide input on these models. We also encourage CMMI to make such waiver information more easily accessible to stakeholders and participants to help ensure compliance with the waiver provision in the CMMI statute.

Finally, while we appreciate CMMI identifying potential waivers, we recommend that CMMI design the Phase I framework in a way that minimizes the number of waivers needed. This is consistent with the statute which allows for waivers when "necessary solely for purposes of carrying out [Phase I]." Because the CMMI statute only authorizes waivers in Phase I models,[4] any waivers used in Phase I could not be continued in a Phase II expansion model. Accordingly, CMMI should clarify how it would adapt the Phase I VBID model to eliminate reliance on waivers if the Phase I model appears successful, so as to ensure the model's continued success if expanded to Phase II, bearing in mind that this adaptation process could be simplified to the extent that Phase I waivers are minimized.

Model Evaluation and Learning Systems

As with CMMI's other models, rigorous evaluation of the VBID Model Test will be important to understand whether and to what extent the flexibilities offered in the model improve quality of care and reduce Medicare spending, as well as the impact of the Model Test on beneficiary access to care. As CMMI moves forward, we encourage continued transparency in the particular measures and methods that will be used to evaluate the impact of the VBID Model Test. Continued opportunities to provide feedback on the evaluation methods and measures will help to ensure that the measure set is sufficiently robust and multi-faceted. In particular, CMMI should ensure that measures of beneficiary health outcomes – including

[4] See Social Security Act (SSA) § 1115A(d)(1). This provision only permits waivers "necessary solely for purposes of carrying out this section with respect to testing models as described in subsection (b) [i.e., 'TESTING OF MODELS (PHASE I)']." (Emphasis added.) The Phase II expansion provisions, by contrast, are separately set out in subsection (c) of SSA § 1115.

intermediate outcomes and patient reported outcomes such as quality of life and functional status – are included in its evaluation of the impact that the VBID Model Test has on enrollee quality of care.

We also understand CMMI's interest in facilitating learning activities related to the implementation and outcomes of VBID so that organizations can improve their designs over the course of the model test. In facilitating these learning activities, CMMI should ensure that plans remain the organizations developing VBID. Therefore, it will be important that CMMI not conduct its own value assessment, or develop a list of high value items, services, providers, disease management or other programs, or additional supplemental benefits based on the information collected from plans. Instead, it should work to ensure that plans meet certain principles for VBID design, including those described above.

Permissible Interventions

PhRMA appreciates that the VBID Model Test allows plans to select one or more of four general approaches to plan design modifications. By allowing plans flexibility in implementing VBID, CMMI increases the opportunity for plans to achieve savings and improve quality. We also strongly support CMMI's requirement that organizations may not propose reductions in enrollee benefits or increases in cost-sharing amounts, which we read as applying across all of a plan's enrollee population, not just those targeted enrollees under the VBID model. It will also be important to ensure that health plans do not substantially reduce the number of drugs on their formularies as part of the VBID model. We offer specific suggestions on several of the plan interventions below.

1. *Reduced Cost Sharing for High Value Services*

   We encourage CMMI to add to the requirements for plans that reduce cost sharing for high value items and services by clarifying that organizations cannot identify high-value items and services based on cost alone. CMMI currently includes such a requirement for plans that reduce cost sharing for high value providers, and this requirement should be extended to items and services. Allowing plans to implement VBID based solely on price would be inconsistent with the definition of VBID, "a system that bases patients' copayments on the relative value—not the cost—of the clinical intervention."[5]

   We also recommend that plans be required to proactively notify manufacturers of items and services, if their product is identified as high value under the VBID model, in advance of the model being finalized. Plans are similarly required to notify providers if they have been identified as high value.[6] Manufacturers of items or services that are not initially identified as high value, but which are used to treat patients in one of the clinical categories defined by CMMI for which a plan has identified a high value item or service, should similarly be notified that their product has not been

[5] ME Chernew and AM Fendrick. "Value Based Insurance Design: Restoring Health To The Health Care Cost Debate." White Paper. 2009. Available at: http://vbidcenter.org/wp-content/uploads/2014/08/health-essay-2009-chernew.pdf.
[6] See page 11 of the Announcement of Medicare Advantage Value-Based Insurance Design Model Test.

designated as high value by the plan. Manufacturers of items or services that are therapeutic alternatives to items and services identified as high value should be notified, not just manufacturers of other medications in the same class. This preliminary notification is an important part of ensuring that manufacturers are given an opportunity to present evidence to participating payers that their product is high value and/or to identify potential gaps in knowledge regarding a product's use or value.

Successful VBID will also require payers to have accurate and comprehensive information about the items and services to meaningfully identify those that are high value. Biopharmaceutical manufacturers collect a broad range of information about their products on an ongoing basis; this information goes beyond what is included in product labeling, and can include data about subpopulations within the approved indication(s) or about medically accepted alternative uses for which the product is listed in recognized compendia or frequently used in clinical practice but which are not currently included in the labeling. Outdated Food and Drug Administration (FDA) regulations currently prohibit manufacturers from proactively communicating with payers about these and any other benefits of their products that are not included in product labeling. To ensure a meaningful discussion between developers and manufacturers of biopharmaceutical products and payers about the value of the product as part of plan VBID development, it will be important for the Food and Drug Administration (FDA) to update its regulations to allow manufacturers to communicate proactively with payers about items/services for the purpose of plan VBID development and refinement. While CMMI cannot waive FDA regulations, CMMI should work with FDA to facilitate greater communication by manufacturers about their products to support the types of innovations that CMMI is seeking to advance.

2. *Reduced Cost sharing for High Value Providers*

PhRMA supports CMMI's focus on the clinical rationale behind identifying high-value providers for each target population, and that CMMI encourages plans to rely on independent, external metrics when determining if a plan is high value. As stated above, allowing plans to implement VBID based solely on cost would be inconsistent with the definition of VBID.

CMMI should also consider whether plans should be required to notify providers who have not been identified as high-value under the VBID model. Such notification may give these providers an opportunity to understand why they are not considered high-value and make any improvements or clarifications needed to be recognized as high value.

Plan Bidding and Projected Savings

PhRMA appreciates the detail on how plans should account for VBID interventions in preparing their bid submissions under the model, and it is our understanding that supplementary actuarial guidance will be forthcoming with the RFA later this month. As outlined in the model announcement, CMMI would treat VBID

interventions as Part C mandatory supplemental benefits for bidding purposes. However, interventions that include reductions in cost-sharing for Part D-covered drugs would still need to be accounted for in the separate Part D bidding process and additional guidance is needed from CMMI to understand how this would be operationalized under the VBID model. This raises some complexities that will be important to the model's success and that CMMI will need to address as this demonstration moves forward.

For example, CMMI should consider addressing how reduced cost sharing may have an impact on Part D bids, which in turn could affect the calculation of Medicare savings under the VBID model. Reducing cost-sharing for Part D-covered drugs inherently makes the benefit more generous, which would therefore increase the cost to a plan of providing the Part D benefit and could increase Part D premium costs for all enrollees in a given plan, whether or not they are a targeted population under the VBID model. Currently, plans prepare a Part D bid based on a uniform benefit structure for their entire enrollee population. As a result, plans may face challenges in pricing their Part D bids for a segmented enrollee population with somewhat different benefits, as envisioned under the VBID model. Further, in order for a plan to achieve net savings for Medicare, CMMI may need to consider allowing MA-PD plans to use savings from anticipated improvements in Part D drug adherence that may help reduce expected Parts A and B costs (and thus reduce the plan's Part C bid) to offset Part D costs that otherwise might have to increase for enrollees, whether or not they have a targeted chronic condition.

Given these significant challenges with operationalizing VBID interventions in the Part D bidding process, PhRMA encourages CMMI to continue working closely with actuaries who prepare Part C and Part D bids each year to address these concerns and ensure that the operation of the VBID model does not result in increased costs or reduced benefits (e.g. less robust formularies or significant formulary changes from year to year) for any beneficiaries, whether or not they are targeted for VBID interventions. Failure to do so may also violate CMMI's stated principle that organizations participating in the model may not discriminate against non-targeted populations.

Process for Announcing and Modifying CMMI Models

PhRMA appreciates the opportunity to provide input to CMMI on the Medicare Advantage Value-Based Insurance Design Model Test prior to the issuance of a Request for Applications, both through the Health Plan Innovation Request for Information issued in 2014 and now through the Announcement Memorandum. PhRMA has consistently advocated for an open, transparent, and accountable process for the development and testing of new models of care that includes opportunity for public comment. Seeking and responding to stakeholder and public input while models are in the development stage is essential for the long term success of alternative payment models (APMs) and will ensure a robust dialogue on the key elements of new models, including payment mechanisms, quality measures, legal waivers, evaluation methods, and other APM implementation issues. Accordingly, we encourage CMMI to continue to announce additional details (e.g., the model evaluation strategy), refinements, and modifications to the Value-Based Insurance Design Model publically to continue this dialogue and support a successful model test.

While we appreciate CMMI's early announcement of the Value-Based Insurance Design Model, we note that the announcement allowed for a limited two-week comment period. As CMMI continues to initiate new Phase I models, announcement of these models in the Federal Register with a 45-day public comment period will also help to ensure that the public and interested parties are fully aware of models being tested and have sufficient opportunity to provide thoughtful input on new model designs.

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PhRMA appreciates the opportunity to provide feedback to CMMI on its Announcement of Medicare Advantage VBID Model Test. PhRMA is committed to working with you on this model moving forward and we welcome the opportunity to discuss our feedback in more detail.

Sincerely,

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