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May 9, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: *Medicare Program; Part B Drug Payment Model* [CMS-1670-P]

Dear Acting Administrator Slavitt:

On behalf of the University of Michigan Center for Value-Based Insurance Design (V-BID Center), I am writing to submit our comments relating to the proposed rule on the *Medicare Program; Part B Drug Payment Model* [CMS-1670-P] (herein referred to as the "Part B Proposal").

We applaud the Centers for Medicare and Medicaid Services (CMS) for their continuous efforts to test, evaluate, and implement innovative pricing, reimbursement, and care delivery models. The V-BID Center recognizes the important contributions made by the Innovation Center to shift healthcare delivery from a volume-driven to a value-based system. The V-BID Center advocates for the use of patient-centered, evidence-based purchasing tools, including those contained in the Part B Proposal. Accordingly, we strongly support the use of reduced or eliminated cost-sharing and indications-based pricing as incorporated in the Proposal.

Value-Based Insurance Design
The University of Michigan Center for Value-Based Insurance Design was established in 2005 to develop, evaluate, and promote consumer engagement initiatives in order to ensure efficient expenditure of health care dollars and maximize clinical benefits of care. The Center is the first academic venue in which faculty with both clinical and economic expertise conduct empirical research to determine the health and economic impact of innovative benefit designs.

The basic V-BID premise is to align patients' out-of-pocket costs, such as copayments, co-insurance and deductibles, with the value of health care services and providers. This approach to designing benefit plans recognizes that specific health services have different levels of value to the patient. Thus, V-BID programs are designed with the tenets of 'clinical nuance' in mind, which recognize that 1) medical services differ in the amount of health produced, and 2) the clinical benefit derived from a specific service depends on the consumer using it, as well as when, where, and by whom the service is provided. By reducing barriers to high-value treatments (through lower costs to patients) and discouraging low-value treatments (through

higher costs to patients), these plans can achieve improved health outcomes at any level of health care expenditure. Studies show that when financial barriers to high-value care are reduced, significant increases in patient adherence with recommended treatments result. The inclusion of reduced cost-sharing and indications-based pricing in the Part B Proposal is an important recognition that clinical nuance is a critical element for the successful implementation of initiatives aimed to improve quality, enhance the patient experience, and control cost growth**.**

Proposal Comments
Drug Pricing
Other stakeholders will submit more detailed comments regarding the proposed changes to the ASP pricing model. We share some of their broad concerns. First, we believe that the scope and scale of the testing are too large, especially given that many of the strategies (save perhaps for reduced cost-sharing) are largely untested by other private and public payers. More importantly, however, we feel that the adoption of this pricing strategy will delay more substantive quality – not cost – driven changes to pharmaceutical pricing in Medicare Part B. Although the proposed reimbursement approach is an improvement from its predecessor, neither the current nor the proposed pricing model is based on the concept of clinical nuance (i.e., drug pricing is not based on the clinical value of the drug to the patient). Clearly, a different payment methodology for appropriate care is necessary to create a systemic switch from "volume to value."

Cost-sharing
As Medicare beneficiaries are asked to pay a greater percentage of their health care expenditures, cost-related non-adherence is an important and growing problem. A robust body of peer-reviewed evidence demonstrates that cost-related non-adherence exists among Medicare beneficiaries for high-value medical services across the entire episode of clinical care, including clinician visits, diagnostic tests, and prescription medications. This sub-optimal use of evidence-based services results in negative clinical outcomes and, in some clinical scenarios, higher aggregate costs to the Medicare program.

Widespread support and strong evidence exist for clinically nuanced cost-sharing. Reducing or eliminating cost-sharing has been recognized as an important public policy measure for balancing costs and quality in health care at the local, state, and federal level. For example, V-BID was incorporated into federal health reform law (Section 2713 (c) of the Patient Protection and Affordable Care Act), eliminating cost-sharing for evidence-based preventive services for over 130 million Americans. In March 2011, V-BID was featured prominently in HHS's National Quality Strategy. V-BID has also been recognized by the Medicare Payment Advisory Commission (MedPAC) in the 2009, 2010, 2011, and 2012 reports to Congress. CMS's implementation of the Value-Based Insurance Design demonstration project in Medicare Advantage -- slated to begin in 2017 in seven states -- will examine whether clinically nuanced cost-sharing for selected services for CMS-specified chronic conditions will lead to enhanced utilization, improved patient-centered outcomes, and lower costs.

This Proposal represents an excellent opportunity to better implement clinical nuance into the Medicare Part B prescription drug model. Unlike other strategies in the proposed rule, the clinical and economic impact of cost-sharing reductions is well studied in both public and private payers. Lowering consumer out-of-pocket costs for high-value visits and drugs have been demonstrated to increase clinician visits, improve medication adherence and lower emergency department visits, while also aligning with value-based provider incentives.

As CMS considers cost-sharing changes for Medicare beneficiaries, we would like to emphasize that low-cost drugs are not always the most valuable option to an individual patient. Specifically, chronic conditions (many relevant to Medicare Part B) often necessitate multiple therapies to achieve desired outcomes. In many clinical scenarios, patients face higher cost-sharing for recommended treatments when first-line therapy does not work or is not indicated. Without other clinically appropriate alternatives, patients are often unable to escape higher out-of-pocket costs for essential medications.

Relevant to the Part B Proposal, our "Reward the Good Soldier" cost-sharing model demonstrates the potential for clinical nuance in a reduced or eliminated cost-sharing strategy. A common oncological example, chronic phase chronic myelogenous leukemia (CML), can illustrate the need for clinically nuanced – not exclusively price based – consumer cost-sharing levels.

Chronic phase CML has three choices for first line oral therapy: imatinib, dasatinib, and nilotinib. Imatinib is available as a generic and is 30% less expensive than the other 2 agents. Thus, dasatinib and nilotinib are usually considered second-generation drugs in many treatment protocols. Although the second-line agents may produce desired outcomes in a shorter duration compared to imatinib, *the three drugs do not differ in terms of overall survival*. While patients with chronic phase CML are prescribed imatinib as the first choice, the outcomes may be significantly different dependent on their course:

- Patient A – prescribed imatinib, tolerates therapy and goes into remission
- Patient B – prescribed imatinib, does not tolerate therapy due to side effects and switches to second-generation
- Patient C – disease progresses because of imatnib resistance and switches
- Patient D – at high risk for accelerated phase and proceeds directly to second-generation

Under the current Medicare benefit design where cost-sharing is based on acquisition cost, patients who are not successful with imatinib (Patients B/C), or for whom imatinib is not recommended (Patient D), will face higher cost-sharing for the recommended second-generation drugs. Increased cost-sharing for second-line medication may lead to non-adherence. Each of these 4 patients is considered a "good soldier" because they followed the required steps for their condition, but Patients B/C/D are penalized because they require an alternative, more expensive option. In the "Reward the Good Soldier" model, those who first

take the less expensive drug as directed (Patient B/C), and or those patients where first line therapy is not indicated (Patient D), would face reduced cost-sharing for the recommended second-generation therapy. This "dynamic" benefit design recognizes that chronic conditions often necessitate multiple therapies to achieve desired clinical outcomes, and that increasing out-of-pocket costs for alternative therapies may prevent consumers from accessing recommended treatments. This dynamic design reflects the varying nature of a clinical condition, commits to established policies that encourage lower cost, first-line therapies, and enhances access to effective therapies when clinically appropriate.

Indications-based pricing
Indications-based pricing -- recognizing that not all medications have equal value across all conditions, patients, and settings -- is a natural extension of clinical nuance and should be fully tested in the Medicare Part B Proposal. Indications-based pricing is relevant for all medical services, yet drug reimbursement often operates in a 'one-price-fits-all' paradigm. The price of the drug (and consumer cost-sharing) is typically not based on clinical benefit, but rather on acquisition cost, and is the same regardless of widely varied clinical benefit provided in different clinical conditions.

It is well accepted that a specific drug, when used in different clinical situations, has different value depending on the relevant indicators. Rituximab and rituximab combination therapy (R-CHOP) -- widely used pharmaceutical therapies in Medicare beneficiaries across multiple clinical indications -- provide a relevant illustration. Rituximab monotherapy is *high-value* for symptomatic marginal zone lymphoma, but *low-value* for Chronic lymphocytic leukemia. R-CHOP is *high-value* in Diffuse large B cell lymphoma as a frontline curative therapy, but is deemed *low-value* in Burkitt lymphoma. Despite wide variation in clinical value across clinical indications, physicians are usually reimbursed based on the price of rituximab. The V-BID Center strongly concurs with the Part B Proposal, in that indications-based pricing is an important step in improving quality and enhancing efficiency.

The V-BID Center believes that certain aspects of the Part B Proposal are important steps towards clinically nuanced pharmaceutical reimbursement under Medicare Part B. Of note, the value-based purchasing tools proposed in the second phase are crucial for aligning payment with value, moving reimbursement beyond the prices of drugs and towards the clinical value they provide patients. It is our strong recommendation that clinically-driven (not price-driven) cost-sharing reductions will be included in the Part B Proposal. These innovative cost-sharing models must take into account that the natural history of many chronic conditions often necessitates multiple therapies to achieve desired patient-centered outcomes. Secondly, the varying value of drugs in different clinical circumstances requires a new reimbursement model. The same pharmaceutical agent can be both high-value and low-value depending on the disease treated or the stage of a specific clinical condition. Thus, reimbursement and consumer cost-sharing should reflect this important clinical nuance.

We support your initiatives to encourage the delivery of evidence-based and cost-effective health care. A clinically nuanced approach to Part B reimbursement and benefit design offers an intuitive and implementable opportunity to align incentives for Medicare providers and beneficiaries to receive the care they need in a way that can lower overall health care cost trends while improving patient-centered outcomes.

Our multidisciplinary team of researchers introduced the concept of Value-Based Insurance Design nearly two decades ago. We have worked with hundreds of public and private health care stakeholders to promote its implementation and evaluation. We are delighted to provide input to this process, and look forward to an ongoing interaction as CMS develops further guidance advancing this important proposal.

Thank you for your attention to this matter. Please contact us if you require any additional information.

Sincerely,

Director
Center for Value-Based Insurance Design (V-BID)
University of Michigan