On October 2, 2014, The Centers for Medicare & Medicaid Services (CMS) released a request for information to test innovations in Medicare health plans.

Specific areas of interest included:
(1) plan design, including but not limited to value-based insurance design (V-BID);
(2) care delivery;
(3) beneficiary and provider incentives and engagement; and/or
(4) network design.

The University of Michigan Center for Value-Based Insurance Design was pleased to acknowledge CMS’s interest in V-BID. The V-BID Center’s response to selected relevant questions in the RFI follows.
14. Would you recommend that CMS implement a model test that would allow VBID for beneficiaries with specific chronic conditions? Yes_ X_ No__

**Motivation for V-BID in Medicare Advantage**

A robust and growing 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 preventive screenings, clinician visits, and prescription medication use.\(^1\)\(^3\) 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.\(^2\) These undesirable clinical and financial effects of cost-related non-adherence are more pronounced for individuals with multiple chronic conditions and/or the most financially vulnerable.\(^2,3\) This important problem warrants targeted policies that reduce financial barriers to ensure that Medicare beneficiaries receive recommended medical care. The accumulating evidence demonstrating the positive effects of value-based insurance design (V-BID) on improving patient-centered outcomes, reducing health disparities, and lowering spending in the commercial sector necessitates a model test in Medicare Advantage (MA) and Medicare Advantage Prescription Drug (MA-PD) plans. We at the University of Michigan Center for Value-Based Insurance Design strongly support a test of V-BID for MA beneficiaries with specific chronic conditions.

**V-BID: An Intuitive, Partial Solution to Cost-related Non-adherence**

Value-Based Insurance Design (V-BID) is built on the principle of lowering or removing financial barriers to essential, high-value clinical services. V-BID plans align patients’ out-of-pocket costs, such as copayments and coinsurance, with the clinical value -- not the acquisition cost -- of services. V-BID programs are designed with the tenets of “clinical nuance” in mind. These tenets 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 and where the service is provided.

Since its inception in 2005, the University of Michigan Center for Value-Based Insurance Design has led efforts to promote the development, implementation, and evaluation of innovative health benefit designs balancing cost and quality. A multidisciplinary team of faculty led by A. Mark Fendrick, M.D., first published and named the V-BID concept and has guided this approach from early principles to widespread adoption in the private and public sectors. The lessons learned from V-BID’s extensive implementation in the commercial sector and state employee health plans across the country offer translatable opportunities for innovations in Medicare Advantage plans and prescription drug coverage. Medicare Advantage plans can capitalize on these successes to increase care quality, improve patient-centered outcomes and reduce health disparities, while also reducing costs.

**The Evolution of V-BID in Medicare Policy**

V-BID has been recognized as an important public policy measure for balancing quality improvement and cost containment in health care at the local, state, and federal level. The first federal V-BID initiative was the introduction of bipartisan Senate bill 1040, “Seniors’ Medication Copayment Reduction Act of 2009,” sponsored by Senators Hutchison (R-TX)
and Stabenow (D-MI) to authorize the Department of Health & Human Services (HHS) to undertake a demonstration of V-BID for high-value prescription drugs within Medicare Advantage plans. While S. 1040 remained in committee, bipartisan support for V-BID grew throughout national health reform deliberations. V-BID was included in every version of House and Senate national health reform bills and was incorporated into Section 2713 of the Patient Protection and Affordable Care Act (PPACA). The implementation of V-BID principles into Sec. 2713 -- by means of the elimination of consumer cost-sharing for specific, evidence-based preventive care services -- has led to enhanced coverage for tens of millions of Americans for over 60 clinical services, including screenings, immunizations, and counseling. V-BID was included in the 2010 HHS guidelines for implementing health reform and was prominently featured in HHS’s National Quality Strategy in March 2011. V-BID has also been recognized as a promising health care reform strategy by the Medicare Payment Advisory Commission Reports to Congress from 2009 through 2012.

Most recently, bipartisan, bicameral legislation, S. 2783/HR. 5183 “The V-BID for Better Care Act of 2014”, was introduced by Senators John Thune (R-SD) and Debbie Stabenow (D-MI) and Representatives Diane Black (R-TN) and Earl Blumenauer (D-OR). This legislation authorizes the Secretary of Department of Health & Human Services to establish a three-year demonstration program allowing participating Medicare Advantage plans to test V-BID principles. Multiple stakeholders from across the ideological and political spectrum support this legislation, including NCQA, AHIP, AARP, and the National Coalition for Health Care Reform.

**EVIDENCE OF V-BID SUCCESS IN COMMERCIAL HEALTH PLANS**

Numerous private and public payers, employers, unions, and business coalitions nationwide have implemented V-BID programs. Private self-insured employers such as Marriott and Pitney Bowes have realized beneficiary health improvements and reported significant savings by implementing V-BID programs. State employee health plans, along with other large employers, provide incentives for individuals with specific chronic health conditions to increase the use of appropriate high-value, health care services. Connecticut State Employees’ Health Enhancement Program, UnitedHealth Group’s Diabetes Health Plan, Aetna, and Blue Shield of California’s “Blue Groove” Plan are among the large employers who have implemented plans that provide incentives for targeted clinical conditions.

Evidence is accruing that reducing consumer cost-sharing leads to the increased use of high-value services. To date, most V-BID programs focus on removing financial barriers to high-value prescription drugs used to treat common, chronic conditions for which evidence-based guidelines exist (e.g., diabetes, asthma, heart disease). A 2013 *Health Affairs* systematic review of V-BID prescription drug programs reported that lowering consumer cost-sharing on targeted drug classes improved adherence, lowered consumer out-of-pocket costs and led to no significant increase in total spending. As V-BID plans are increasingly implemented in the self-insured and fully insured commercial markets, the recognition of plan features that predict clinical and economic success is accumulating.
**Why Medicare Advantage?**

In contrast to FFS Medicare, private health plans participating in MA have the flexibility to use care management techniques to promote evidence-based care, including a limited ability to adjust benefit design. The compendium of MA tools includes network formation, provider facing-interventions (e.g., bonuses for quality and high performance), and utilization management programs to identify under-utilization as well as over-utilization. From the consumer engagement perspective, however, MA plans could further enhance their ability to serve beneficiaries if they had greater ability to use benefit design and clinically nuanced cost-sharing to promote value.

Specifically, outside of the proposed V-BID demonstration, MA plans are not allowed to tailor benefits to specific sub-groups of patients, such as those with a diagnosed clinical condition, for whom a given service may provide particularly high value. Without this flexibility, it is impossible to design appropriate V-BID tools like the ones described above. Currently, if MA plans try to encourage the use of a specific service by lowering copays, they must lower copays for everyone in the plan, even though clinical appropriateness for specific patients may vary widely. For example, it is not clinically appropriate for all Medicare beneficiaries to receive annual eye exams, but it is clinically indicated for all Medicare beneficiaries with a diagnosis of diabetes to receive this service.

Implementing clinically nuanced benefit designs to copayments and coinsurance for the purpose of targeting high-risk/high-spending beneficiaries would give Medicare Advantage plans a necessary tool to incentivize/motivate those individuals to pursue and receive clinically indicated high-value services and mitigate the well-documented problem of cost-related non-adherence. The flexibility to target enrollee cost-sharing based on clinical information (e.g., diagnosis, clinical risk factors, etc.) is a crucial element to the safe and efficient allocation of Medicare expenditures. Thus, applying techniques that are successfully utilized in the commercial health insurance market into a V-BID model test plan in MA offers an opportunity to increase utilization of evidence-based services, enhance patient-centered outcomes, lower aggregate health care costs, and reduce health care disparities among a target-rich population.

**Citations:**
15. What factors and design principles should CMS consider if it were to develop such a model test? Some potential factors to consider are which chronic conditions and characteristics of the population to target, which quality measures to track, and what beneficiary protections to include.

For several reasons, Medicare beneficiaries would significantly benefit from incorporating V-BID principles into MA and MA-PD benefit designs for specific chronic conditions. Both traditional Medicare and MA plans have generous benefit designs for evidence-based, primary preventive services (e.g., wellness visits, immunizations, screenings). A V-BID demonstration in MA plans would extend the principle of clinically nuanced cost-sharing for evidence-based services used to manage common chronic conditions. These conditions cause significant morbidity and mortality among Medicare beneficiaries and drive a substantial majority of Medicare spending (primary prevention accounts for less than 5% of spend).

As a whole, Medicare beneficiaries often have complex needs and multiple chronic conditions. About 45% of Medicare beneficiaries are living with three or more chronic conditions, 28% report fair or poor health, and about 17% have multiple functional limitations. Additionally, Medicare beneficiaries often have limited financial resources, with the majority living on less than 200% of the federal poverty line and spending a significant proportion of their income on health care. As a result, out-of-pocket costs are a sensitive component of Medicare for many beneficiaries. In fact, the oldest and poorest beneficiaries spend more than a quarter of their income on health care, and a growing number of elderly and disabled enrollees account for a disproportionate share of total spending.

**V-BID Best Practices Should Drive Design**

Longstanding experience and variation in elements of V-BID programs implemented in the private sector can provide useful information regarding the establishment of a successful V-BID demonstration in Medicare Advantage plans. A 2014 *Health Affairs* evaluation of 76 V-BID prescription drug programs identified specific design features that predicted significant impact on improvement in medication adherence:¹

- Magnitude of reduction in cost-sharing levels
- Targeting of high-risk individuals
- Offered with a wellness program
- Implemented without a concurrent disease management program
- Used mail-order prescription delivery

**Design Tools**

A prerequisite of a V-BID program is the provision of incentives so that individuals with specific clinical indications are encouraged to access the care they need in the most appropriate setting. This requires the abandonment of the “one-size-fits-all” cost-sharing models that do not acknowledge the heterogeneity in benefit of clinical services across diverse patient populations.
A number of plan design tools can be used to incentivize patient behaviors in V-BID programs including:

- Cost-sharing provisions for targeted services or providers
- Premium reductions
- Deductible waivers
- HSA contributions
- Access to enhanced benefits or programs
- Other financial rewards [gift cards, raffle entries, etc.]

V-BID initiatives are typically structured for specific health conditions. The majority of these plans’ design tools are applied towards diagnostic tests, treatments, and monitoring of chronic diseases for which evidence-based guidelines are available. Some examples regarding chronic conditions and related services include:

- Asthma: controller medications, spirometers
- Cardiac disease: cholesterol testing, smoking cessation, secondary prevention medications (e.g., statins, beta-blockers)
- Diabetes: blood glucose monitors, test strips, prescription medications, urinalysis, eye and foot examinations
- Hypertension: nutritional counseling, blood pressure cuff, prescription medications
- Depression: behavioral therapy, prescription medications

QUALITY MEASURES

The efficacy of an incentive-driven plan design tool can be measured by a number of clinical and/or financial outcomes depending on the structure of the V-BID program. It is common to assess the impact of V-BID plans using the following measures that often quantify the use of services designated as quality metrics by specialty society guidelines or independent organizations (e.g., NCQA and NQF):

- Utilization of targeted high-value services [e.g., diabetic eye exam, prescription drug adherence]
- Impact on specific populations [e.g., race/ethnic group, low income]
- Setting of care delivery [e.g., ambulatory, in-patient setting]
- Clinical outcomes [e.g., cardiovascular events, emergency room visits]
- Patient satisfaction
- Medical expenditures [e.g., condition specific, total medical spending]

BENEFICIARY PROTECTIONS

Improving the health outcomes and quality of life of the beneficiary has always been the focal point of V-BID programs. CMS should ensure that protections are in place to guarantee that the basic V-BID principles -- reduction or removal of financial barriers to high-value evidence-based care -- are available to all eligible enrollees in plans offering a V-BID demonstration.
I. **Prohibition of Increases of Copayment or Coinsurance**

The aim of V-BID programs is to facilitate access to evidence-based services for specific patient populations. Therefore, **we strongly advocate that programs in a V-BID MA and MA-PD demonstration be limited to those that exclusively lower cost-sharing**. We fervently believe that in no case may any Medicare Advantage plan participating in the demonstration program increase the amount of copayments or coinsurance for any item or service covered under such plan for purposes of discouraging the use of such item or service.

II. **Open Access for Beneficiaries with Targeted Conditions**

V-BID programs within the Medicare Advantage demonstrations must be freely available for all eligible individuals diagnosed with the targeted clinical conditions -- regardless of duration, severity or other factors. To maximize participation, we believe that the demonstration should not require the beneficiary to “opt-in,” nor should there be barriers required for enrollment. These potentially onerous administrative policies would simply increase obstacles for enrollees to access the benefits of V-BID in managing chronic diseases and would likely reduce enrollment for vulnerable populations who might benefit the most from the program.

There is room for new models to improve the clinical and financial outcomes in the Medicare population for the following reasons:

1) Over half of Medicare beneficiaries have at least two chronic clinical conditions
2) Management of chronic conditions plays an essential role in determining patient-centered outcomes
3) Chronic conditions account for more than 90% of Medicare spending
4) Cost-related non-adherence is prevalent in Medicare beneficiaries

The documented positive impact of V-BID in the commercial sector, coupled with the target-rich environment of the MA program, justifies a test of V-BID to demonstrate whether clinically nuanced cost-sharing can improve patient-centered outcomes and enhance efficiency in Medicare spending.

Citations:

16. What changes in cost-sharing elements, such as co-pays, MOOPs, deductibles, and/or premiums, (cost-sharing) should be varied and what would be the intended impact of these changes? Should there be any restrictions on the magnitude of such changes? What existing requirements or standards present a barrier to implement such changes?

The aim of a V-BID demonstration is to provide MA plans greater flexibility to lower beneficiary cost-sharing for recognized high-value, evidence-based services, clinicians, and facilities. These out-of-pocket reductions for beneficiaries should extend to all MA cost-sharing elements (e.g., co-pays, MOOPs, deductibles, and/or premiums). Such increased flexibility would permit MA plans to promote value in clinically appropriate ways that are proven to improve quality. The intended impact is to provide adequate incentive for the consumer to receive clinically indicated care. Moreover, through its ongoing review of plan benefit packages, CMS can continue to ensure that such benefit designs are not discriminatory and promote value for beneficiaries with complex needs.

The V-BID Center does not recommend that a specific limit be placed on the magnitude of cost-sharing reductions for the specific services in targeted populations with chronic conditions. This is best left up to the MA plans. The V-BID provisions in Section 2713 of PPACA eliminate consumer cost-sharing for high-value primary preventive services. A review of 76 V-BID prescription drug programs identified the magnitude of reduction in cost-sharing levels as the most impactful plan element leading to improvement in medication adherence. In certain instances in the commercial market, some payers have gone beyond cost-sharing elimination and provided additional financial incentives (e.g., direct payments, premium reductions, lotteries) for utilizing certain services that were deemed to be of high value (e.g., smoking cessation programs, completing health risk assessments).

**Existing Barriers to Implementation**

Outside of this demonstration, 1) MA plans are not allowed to tailor benefits and/or cost-sharing requirements to specific sub-groups of patients who may receive particularly high value from a given service, and 2) MA plans are not allowed to vary copayment for specific high-value providers within the designated network. Without this flexibility, it is impossible to design appropriate V-BID tools that take advantage of the fact that the clinical value of a specific medical service depends on the individual beneficiary, the provider and where the service is delivered. Currently, if MA plans try to encourage the use of a service for a specific population by lowering copays (e.g., retinal eye exams for beneficiaries with diabetes), they must lower copays for that service for everyone in the plan, even though appropriateness for specific patients and clinical conditions may vary widely.

**Citations:**
17. Please include a description of how (by what mechanism) your proposed model design would produce net savings to CMS without adversely impacting patient care or outcomes.

**V-BID Savings Require Offsets from Other Clinical Services**

The financial impact of V-BID programs on health care spending depends on the level and precision of clinical targeting and the extent of the changes in consumer cost-sharing copayments. Since many clinical services provide higher value for a select subset of patients, the better the system is at identifying those patients, the greater the likelihood of achieving a high financial return. More careful targeting of interventions results in lower program costs, because fewer individuals are eligible for copayment reductions. This is why the MA demonstration should focus on specific chronic conditions.

From an actuarial standpoint, offsetting the added short-term costs of collecting lower consumer copayments and the related increased use of high-value services are the savings incurred by reductions in future adverse events, which are avoided by achievement of better clinical outcomes. For example, the increased direct costs of lowering patient cost-sharing for COPD control medications would be at least partially offset by savings resulting from fewer emergency room visits and hospitalizations for acute COPD exacerbations.

The net financial benefit of the V-BID program improves if:

- The underlying risk of an adverse outcome is high in a targeted population;
- The cost of that adverse outcome is high;
- Consumers are responsive to lower copayments; and,
- The service is effective at preventing the adverse outcome.

Additional return on investment accrues if the non-medical benefits of improved health are considered, such as reduced disability and absenteeism, and lower caregiving costs.

**V-BID to Encourage Specific Services**

A *Medical Care* review of the literature on the financial impact of changes in patient copayments found that cost offsets do occur, particularly among those with chronic diseases.¹ Several studies assessed how higher patient copayments for drugs – leading to decreases in prescription drug spending – resulted in utilization of non-drug services such as hospitalizations, emergency room visits, etc. Offsets tended to be higher in the more targeted populations with chronic medical diagnoses. More recently, evidence from V-BID programs in the commercial populations demonstrated that most modestly improve adherence at no additional cost.

In the MI-FREEE trial, commercially-insured individuals who had experienced a myocardial infarction (i.e., heart attack) were randomly assigned to either usual prescription coverage or prescription coverage without cost-sharing for any generic or brand-name angiotensin-converting enzyme (ACE) inhibitor, angiotensin receptor blocker, beta-blocker, or statin. The enhanced prescription coverage group experienced improved medication adherence, lower
rates of additional major vascular events, and decreased patient spending without increasing overall health costs.\textsuperscript{2}

A secondary analysis of the MI-FREEE study was performed to examine the effect of the V-BID program on racial disparities. At baseline, nonwhite patients enrolled in the MI-FREEE study were less adherent with prescribed medication and had higher health care spending than their white counterparts. After cost-sharing was eliminated for the intervention group, adherence to beta-blockers and statins significantly improved for nonwhite enrollees, and a trend toward improved adherence for all three study medications was noted among nonwhite patients. Compared to nonwhites with standard cost-sharing, nonwhite patients without cost-sharing experienced significantly lower readmission rates and a 70\% reduction in total health care spending.\textsuperscript{3}

\textbf{In evaluating the value of a treatment or service, a primary consideration is whether the service provides clinical benefits that are supported by high-quality evidence and whether these clinical benefits provide value by producing improved health outcomes.} Any cost savings associated with adherence to a particular medication therapy (e.g., prescription drugs used to treat diabetes) must be viewed in terms of the long-term improvement to the overall health of those individuals and not just the impact on the specific disease state. The ultimate goal of V-BID programs is to improve the health of individuals by improving the care they receive.

It is the V-BID Center’s position that assessments of value cannot be based on cost alone; the critical components of quality and patient-centered outcomes are of similar import. Most of the high-value preventive services fully covered by Section 2713 of PPACA do not lower health expenditures. \textbf{Improvements in quality and clinical status of patients with chronic conditions – and the savings that are incurred as a result of health improvement – take time.} Most actuarial assessments, including those undertaken by the U.S. Congressional Budget Office (CBO) and most published academic literature, systematically underestimate the clinical and economic benefits of preventive care and the management of chronic diseases in that they use too short of a time window to measure the full impact. That said, in November 2012, CBO acknowledged, “a body of research has… developed that demonstrates a connection between prescription drug use and the use of medical services.” CBO now estimates that “a 1 percent increase in the number of prescriptions filled by beneficiaries [will] cause Medicare’s spending on medical services to fall by roughly one-fifth of 1 percent.”\textsuperscript{4} It is important to note that these CBO calculations included all medications and the entire Medicare population, and, therefore, lack clinical nuance.

Evidence from targeted commercial V-BID programs as well as modeling studies of targeted V-BID interventions in Medicare (e.g., ACE inhibitors for beneficiaries with diabetes\textsuperscript{5}) suggest that health improvements and cost savings are likely to occur when V-BID programs are targeted to high-value services for beneficiaries with specific chronic conditions.
**V-BID to Encourage Specific Providers**

A 2010 *New England Journal of Medicine* study examined the effects of increased copayments for ambulatory visits for Medicare Advantage beneficiaries. When copayments increased for primary and specialty care ambulatory appointments, visits fell significantly. Hospitalization rates rose for those facing higher cost-sharing, as did total expenditures. Importantly, the adverse effects of higher cost-sharing were worse in low-income individuals and beneficiaries with chronic illness.

The implications to Medicare of using V-BID to encouraging patients to choose high-performing providers based upon the cost and quality of care are substantial. A recent report from The Commonwealth Fund Commission on a High Performance Health System estimated that substantial savings would accrue to Medicare over 10 years if we were to “develop a value-based design that encourages beneficiaries to obtain care from high-performing care systems.” Additionally, the June 2011 MedPAC report to Congress summarized findings from the coronary artery bypass graft demonstration project, which selected seven sites based on price, quality of care, and geography. The evaluation found that the project generated interest among providers, reduced costs to Medicare and most participants, and increased quality of care.

**Citations:**

18. Are there other flexibilities or changes to Medicare policies or regulations (in addition to changes to cost-sharing) that you believe could enhance plans’ abilities to successfully implement VBID?

See our response to question 16 in addition to the response below.

CMS should issue clear guidance that provides greater flexibility for MA plans to develop focused networks of high-value providers, including care managers and pharmacists to deliver evidence-based interventions to targeted beneficiary populations. MA plans are allowed to create a provider network, but their ability to vary copayments for providers within that network is limited. Such a policy would be consistent with other Medicare initiatives, including those promoting establishment of patient-centered medical homes and accountable care organizations, which are designed to achieve greater quality and efficiency not only for Medicare beneficiaries but for all consumers.

The primary principles behind payment reform are to reward high-performing providers for achieving quality measures, increase use of preventive care, and decrease overuse of low-value services -- all based on evidence-based medicine. For the health care system to become efficient, it must achieve an alignment of incentives, both non-financial and financial, for all stakeholders. Consumers should have minimal or no barriers to accessing those services for which providers receive incentives; if they do, this constitutes a direct conflict with the fundamental tenets of these initiatives.
20. Are there other considerations that CMS should take into account when designing a V-BID model?

Diverse and respected policy centers and stakeholder coalitions across the ideological and political spectrum have presented plans for reforming the U.S. health care system, including Bipartisan Policy Center, Brookings Institution, The Commonwealth Fund, Kaiser Family Foundation, National Coalition on Health Care, Partnership for Sustainable Health Care, and Urban Institute. All of the reform proposals point toward a common outcome -- better alignment of health care cost inflation while ensuring access to appropriate evidence-based services for all. Each of these proposals explicitly supports value-based payment reform and V-BID.¹

We support CMS's efforts to pursue payment strategies and plan designs focused on promoting clinical effectiveness to maximize value for every health care dollar spent. A substantial amount of energy, sophistication, and resources are being applied to “supply-side” initiatives aimed at changing clinician practice, such as payment reform, health information technology and practice redesign. Unfortunately, these “supply-side” initiatives have paid little attention to consumer decision-making or the “demand-side” of care-seeking behavior. Consumer engagement initiatives such as V-BID and shared decision-making that motivate individuals to access clinical care based on quality and cost information can enhance the quality of care and reduce health care spending.

CMS and other payers are actively implementing models that provide incentives to clinicians to recommend the right care, to the right patient, in the right venue, at the right price. It is of critical importance that consumer incentives are similarly aligned. As Medicare moves from a volume-driven to a quality-driven reimbursement model, it is irrational that Medicare benefit designs place barriers that restrict patient access for those same high-quality services for which a clinician, a PCMH, and an ACO are benchmarked. While the synergies of aligning clinician and consumer incentives around evidence-based clinical services might seem obvious, the reality that a beneficiary is exposed to high levels of cost-sharing for services designated as quality metrics (e.g. NQF, NCQA) is a classic illustration of misaligned incentives.

The ultimate test of health reform will be whether it improves health and addresses rising costs. By incorporating V-BID principles into MA programs, provider and consumer incentives can be truly aligned around the goals of the Triple Aim. This alignment of provider- and consumer-facing incentives will facilitate a shift toward a delivery system that rewards both patients and providers for delivery of high-value, evidence-based care. Adding clinical nuance into payment reform and consumer engagement initiatives can help improve quality of care, enhance patient experience, reduce disparities, and contain cost growth.

Citations: