V·BID University of Michigan
Center for Value-Based Insurance Design

February 28, 2011

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: HHS-OS-2011-0001-0001
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information Regarding Value-Based Insurance Design in Connection with Preventive Care

Submitted via: www.regulations.gov

Dear Sir/Madam:

Thank you for soliciting comments on the subject of Value-Based Insurance Design (V-BID) in the December 28, 2010 Request for Information (RFI) in Connection with Preventive Care Benefits, pursuant to Section 2713 of the Patient Protection and Affordable Care Act (PPACA). The University of Michigan Center for Value-Based Insurance Design appreciates your efforts to implement V-BID as part of PPACA and we welcome this opportunity to offer input to this process. We believe that V-BID offers one of the simplest yet most promising opportunities to encourage clinically-effective care by creating incentives for Americans to get the preventive care they need in a way that can lower overall health care cost trends and improve total health outcomes.

The University of Michigan Center for Value-Based Insurance Design was established in 2005 to develop, evaluate, and promote value-based insurance initiatives to ensure efficient expenditure of health care dollars and maximize 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 Request for Information addresses many of the issues and complexities of plan design that must be understood in order to implement federal V-BID policy. We hope that insights from the multi-stakeholder academic, public, and private sector knowledge base will inform the Departments' process moving forward. In addition to our attached responses, we wish to emphasize three themes with respect to the development of V-BID that are supported by the evidence we present in our responses:

1. **WE SUPPORT THE DEFINITION OF VALUE-BASED INSURANCE DESIGN INCLUDED IN THE JULY 19, 2010 INTERIM FINAL RULES (IFR) FOR GROUP HEALTH PLANS AND HEALTH INSURANCE ISSUERS RELATING TO COVERAGE OF PREVENTIVE SERVICES UNDER PPACA, AND BELIEVE IT REPRESENTS THE INTENT OF CONGRESS**

The legislative history of PPACA demonstrates broad support from bipartisan congressional leaders for using V-BID to improve health and provide more efficient care delivery. We affirm the definition of Value-Based Insurance Design as written on page 41729 of the IFR:

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> "Value-based insurance designs include the provision of information and incentives for consumers that promote access to and use of higher value providers, treatments, and services."

Language incorporating V-BID principles was included in every version of comprehensive health reform legislation throughout the legislative process; we believe the IFR has captured accurately the intent of Congress.

2. SECTION 2713 IS A V-BID IMPLEMENTATION; THE USE OF V-BID WILL RESULT IN THE ENHANCED USE OF CLINICALLY EFFECTIVE PREVENTIVE CARE

The prohibition of patient cost sharing for selected evidence-based screenings and preventive care for specified populations of children, adolescents, and adults is consistent with core V-BID principles: 1] health care services differ in the health benefits they produce; 2] barriers to the use of clinically effective care should be eliminated; and 3] the clinical benefit of health care services depends on the individual who receives them. These principles are germane to the implementation of clinically effective preventive care as authorized by Section 2713, wherein Congress acknowledged that all preventive services are not equal in terms of their clinical value, and selected services do not offer the same clinical value to every person or patient group.

3. V-BID PRINCIPLES SHOULD BE APPLIED BEYOND PRIMARY PREVENTION; WE LOOK FORWARD TO CONTINUING A DIALOGUE WITH THE DEPARTMENTS TO ADVANCE THE ROLE OF V-BID

We believe that the V-BID premise of reduced patient cost sharing for high-value, evidence-based care has important implications beyond preventive services as mandated in Section 2713. The definition of preventive services in PPACA is narrow, focusing only on primary prevention, while secondary prevention has traditionally been a common and successful clinical area of implementation for V-BID plans. Given this experience, we believe V-BID holds important implications for essential benefit packages and offerings in the state health care exchanges.

The University of Michigan Center for Value-Based Insurance Design is delighted to provide you with the attached responses, and we look forward to working with the Departments to help ensure continued flexibility and viability for V-BID innovations. Please contact me if I or my colleagues can answer any questions, provide you with additional information, or be helpful to you as you continue to develop this important policy area in efforts to improve Americans' health and control rapidly rising costs.

Sincerely,

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Responses to the Request for Information

1. **What specific plan design tools do plans and issuers currently use to incentivize patient behavior, and which tools are perceived as most effective (for example, specific network design features, targeted cost sharing mechanisms)?**
    a. **How is effective defined?**

The basic premise of value-based insurance design [V-BID] is to remove barriers to essential, high-value health services. V-BID plans use a variety of financial and non-financial incentives to encourage patients to use evidence-based treatments or services that will improve their health. The most commonly implemented V-BID model limits/reduces co-payments or other patient cost sharing for certain classes of prescription drugs, diagnostic tests and procedures that benefit individuals identified as having a chronic condition. V-BID programs are often tied to wellness/prevention initiatives because V-BID programs become more effective when at-risk populations are identified through the wellness mechanism. For example, an individual who participates in a health risk assessment (HRA) and is identified as being at-risk for heart disease could then receive statins at reduced cost sharing pursuant to a V-BID model.

Plan design tools used to incentivize patient behaviors in V-BID programs include:

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

Although this list is not exhaustive, it includes the major categories of incentives provided by V-BID plans.

The standard V-BID program provides an incentive in the form of lower cost sharing so that individuals get the care they need in the most appropriate setting. By removing barriers to high value services and providers, V-BID programs strive to meet the following objectives:

- Obtain the greatest positive health impact from medical expenditures
- Create an opportunity to restructure health benefits and to change the focus of the health care debate away from cost alone, to the clinical value of health services
- Mitigate the lack of adherence to evidence-based services that results from high cost sharing levels

The efficacy of an incentive can be measured by various clinical and/or financial outcomes depending on the structure of the V-BID program and the targeted patient population. It is common for health plans to assess the impact of V-BID plans on the following measures:

- Utilization of recommended high value services [e.g. – colorectal cancer (CRC) screening]
- Clinical outcomes [e.g. – CRC cases detected, stage at CRC diagnosis]
- Setting of care delivery [e.g. – ambulatory/in-patient setting] or
- Medical expenditures [e.g. – total spending on CRC]

These evaluation approaches are based on a number of factors including:

- An assessment of what works best with a specific population
- Employer and individual choice in benefit design and coverage options
- Clinical information and research on the effectiveness and value of health care services

It should be noted that provider steerage and network designation have not specifically been considered part of the typical V-BID programs. This is largely due to the fact that network designs have been commonly used by health plans for decades, and these network relationships are subject to comprehensive and detailed state regulatory requirements, including network adequacy requirements. Regulators should be cautious of designing any new regulations for providers and networks in relation to V-BID and preventive services.

V-BID programs – aimed to increase the utilization of evidence-based preventive services and those that enhance the management of chronic diseases - are in a dynamic phase of implementation and evaluation. *Given that there is no single "ideal" V-BID program, flexibility is warranted to allow plans to tailor the appropriate incentives – based on clinical context - to change consumer behavior and ultimately encourage patients to use appropriate high-value preventive services and providers.*

2. Do these tools apply to all types of benefits for preventive care, or are they targeted towards specific types of conditions (for example, diabetes) or preventive services treatments (for example, colonoscopies, scans)?

V-BID has been implemented for both preventive and chronic care. There are four basic approaches to V-BID:

1. Design by service. Waive or reduce copayments or coinsurance for select drugs or services, such as statins or cholesterol tests, no matter which patients are utilizing them. This is the strategy employed by Pitney Bowes, which in 2002 reduced the copayments for drugs that treat asthma, diabetes and hypertension. Marriott International, Inc., adopted a similar approach for drug classes used to treat diabetes, asthma and heart disease. Any user of the specified high value service received a lower co-payment, regardless of the clinical indication.

2. Design by condition. Waive or reduce copayments or coinsurance for medications or services, based on the specific clinical conditions with which patients have been diagnosed. This approach is illustrated by the University of Michigan Focus on Diabetes Program, which lowered copayments for selected evidence-based medications and services for employees with diabetes. United Health Group offers a "Diabetes Health Plan" to self-insured customers based on this disease-specific model. In such programs, patients must have a specified clinical diagnosis to receive lower patient cost sharing.

3. Design by condition severity. Waive or reduce copayments or coinsurance for high-risk members who have clinical evidence of disease severity/complications. Aetna has a V-BID program that provides subsidized evidence-based medications for those individuals who have suffered an acute myocardial infarction – a severe complication of coronary artery disease. Others waive patient copayments for asthma medications for those who have needed an emergency room visit or hospital admission for their disease.

4. Design by disease management participation. An extension of the third design approach, this V-BID solution provides reduced or waived copayments or coinsurance to high-risk members who actively

participate in a disease management program. The City of Asheville Project highlighted this approach through offering free medications and testing equipment only for diabetics who attended educational seminars. Wisconsin-based QuadMed, a subsidiary of QuadGraphics, sponsors eight worksite clinics and three pharmacies that play an integral role in its value-based insurance design. Employees who utilize an onsite clinic have a lower copayment than that for alternative care sites. Moreover, if they choose a Preferred Provider Organization network, employees pay a lower coinsurance rate for an office visit than for non-preferred network physicians. In addition, employees earn financial incentives if healthy behaviors are achieved, such as exercising three times a week or reaching certain clinical benchmarks, like improvement in diabetes management measured by reductions in HbA1c levels.

V-BID initiatives are typically structured for a specific population or health condition. Some current examples include:

- Encouraging patients with asthma to follow recommended services by reducing or waiving co-pays for spirometers, and controller asthma medications.
- Waiving co-pays for secondary prevention medications like statins and beta-blockers for patients who have had a myocardial infarction (MI).
- Encouraging patients with diabetes to better manage their hemoglobin A1c levels by providing free blood glucose monitors, test strips, and prescription medications.
- Offering comprehensive tobacco cessation programs with no out-of-pocket costs.
- Offering visits to in-network primary care providers at no cost to the patient.
- Offering behavioral and pharmaceutical therapy for patients with depression with no cost sharing.
- Offering on-site influenza immunizations at no cost to employees.
- Offering on-site screening for blood pressure, blood sugar, and cholesterol at no cost.
- Encouraging patients with hypertension to undergo nutritional counseling and adhere to prescription therapies as recommended in evidence-based guidelines through a reduction or waiver of co-pays.

The majority of these tools are applied to the diagnosis, treatment and monitoring of chronic diseases, such as heart disease, hypertension, obesity, asthma, and diabetes. **Many payers have provided first dollar coverage for high-value preventive services, such as those designated by Sec 2713, for long periods of time, though not necessarily in conjunction with a formal V-BID implementation.** By definition, the implementation of a V-BID program depends on the clinical context of the condition, service, or treatment in question. *Given this emphasis on clinical nuance, it is our hope that plans will have flexibility to provide incentives to targeted individuals to engage in behaviors that will increase the use of evidence-based services and ultimately improve clinical outcomes.*

3. **What considerations do plans and issuers give to what constitutes a high-value or low-value treatment setting, provider, or delivery mechanism?**

    a. **What is the threshold of acceptable value?**
    b. **What factors impact how this threshold varies between services?**
    c. **What data are used?**
    d. **How is quality measured as part of this analysis?**
    e. **What time frame is used for assessing value?**
    f. **Are the data readily available from public sources, or are they internal and/or considered proprietary?**

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.[1] **The goal of V-BID programs ultimately is to improve the health of individuals by improving the care they receive.** For example, if an individual with heart disease participates in a V-BID program that reduces or eliminates their cost sharing for statins and nutritional programs, the "value" of the V-BID program is measured by whether that individual remains healthier over the long-term and avoids costly hospitalizations. V-BID programs frequently increase costs and utilization in the short term with the goal of improving health and decreasing the likelihood of long-term costly illness.

Clinical data – preferably outcomes instead of clinical processes – are essential for assessing quality of treatment setting, delivery mechanism, or provider. **It is the V-BID Center's position that assessments of value cannot be assessed based on cost alone – the critical component is quality.** Plans and issuers have used various quality metrics to determine high- and low-value providers, networks, and hospitals for many years. Quality measurement is a longstanding aspect of health system evaluation. There are numerous widely accepted quality measurement techniques for many of the clinical services recommended by Section 2713.

The main sources of data used by plans to determine high- and low-value services or settings include:

- Medical claims
- Pharmacy claims
- Laboratory claims data
- Satisfaction surveys
- Health risk assessments
- Utilization management programs
- Registries
- Disease management programs

Several quality metrics are available to assist plans in threshold designating high-quality/high-value care [services and/or providers]:

- USPSTF
- ACIP
- CDC
- NCQA / HEDIS
- NQF
- Integrated Healthcare Association
- Profession society guidelines/Disease Management Programs
- Tufts Center for the Evaluation of Value and Risk in Health
- Blue Cross Blue Shield Technology Assessment Center

[1] Most actuarial assessments, including those undertaken by the U.S. Congressional Budget Office and most published academic literature, systematically underestimate the clinical and economic benefits of preventive care in that they use a too short a time window to measure the full impact of disease prevention.

It is our view that in most cases, regulations should *not* designate these services, and instead allow plans to work with the clinical community in designating services/providers.

In the near future, several new sources of data should greatly expand the effectiveness of V-BID programs and the ability to closely track outcomes. The development and adoption of electronic health records will provide an extremely detailed and valuable information resource for evaluating the impact and effectiveness of V-BID programs on an individual patient basis. Additionally, the support provided by the Affordable Care Act for comparative effectiveness research will provide clinical evidence on the effectiveness of care that will drive and support even more value-based decisions.

Since there is no single, widely accepted research metric that allows comparisons of the value of medical services across clinical conditions [the quality adjusted life year (QALY) is used primarily for research purposes], we recommend that the designation of value should be driven by the role of specific interventions by clinical indication. In fact, there is no threshold definition for "value" in V-BID because quality is always a context-specific assessment. Value must always be determined on a case-by-case basis using the quality metric that best suits the data available and the disease or condition in question.

Although the data available today for designating high- and low-value services are imperfect, the use of any clinically rigorous data in benefit design development represents a great improvement in value for patients and plans over the "one-size fits all" cost sharing designations that V-BID programs replace. Further movement toward clinical nuance in cost sharing will only enhance the public's benefit.

Finally, the focus of the Center for Value-Based Insurance Design has been on the evidence-based designation of, and removal of patient barriers to, high value services – rather than providers. **We support the designation of high- and low-value providers when quality metrics are explicitly used in this process.** Provider networks based on cost alone – without a quality component – should not be considered high or low value. However, when quality measures are explicitly used in network creation to steer patients to a particular setting (e.g. ambulatory vs. inpatient) or modality (e.g. laparoscopic surgery vs. open) where there is no difference in quality, but evidence of lower cost, we would view that as comprising acceptable value.

4. What data do plans and issuers use to determine appropriate incentive models and/or amounts in steering patients towards high-value and/or away from low-value mechanisms for delivery of a given recommended preventive service?

There is no single, widely accepted incentive model used in V-BID plans. In general, plans use multiple data sources such as surveys, claims data, prescription information, and results of screenings and diagnostic tests to determine incentive systems. Most patient incentives are "up-front", while other pilot programs require patients to perform a task [e.g., fill out health risk assessment, visit a health coach] in order to receive V-BID benefits. Evaluations of V-BID programs focused on high-value pharmaceuticals report that when compared to control groups, the use of high value drugs are increased by those in V-BID plans, without adding to aggregate medical expenditures. Moreover, since our own research demonstrates that existing cost sharing programs worsen socioeconomic disparities in care delivery, it is possible that the implementation of V-BID programs will likely decrease – but not eliminate – disparities for targeted evidence-based preventive services and interventions for chronic conditions.

As numerous V-BID pilots with varied incentive models are being implemented, the V-BID Center is in the process of gathering more information about how plans determine the structure or appropriateness of incentives chosen, and how these different models impact utilization, quality and cost of care. In the

meantime, until these alternative approaches are rigorously evaluated, we believe that regulations should allow plans the ability to experiment and innovate and not be locked into a single incentive approach.

5. **How often do plans and issuers re-evaluate data and plan design features? What is the process for re-evaluation?**

    a. **How is the impact of V-BID on patient utilization monitored?**
    b. **How is the impact of V-BID on patient out-of-pocket costs monitored?**
    c. **How is the impact of V-BID on health plan costs monitored?**
    d. **What factors are considered in evaluating effectiveness (for example, cost, quality, utilization)?**

Frequency of a plan design evaluation by the issuer depends upon the specific product and its goals. In the case of new offerings [e.g. Consumer-Directed Plan, V-BID program] an issuer may monitor these new products more closely after release to ensure that it is attracting the volume of business and the demographic that was targeted. Typically plans evaluate results on an annual basis or based on the entire contract period, normally two to three years, using the data sources described above. A 2010 employer survey conducted by the Center for Health Value Innovation found that nearly two-thirds of V-BID plans have been in place for less than four years, so there are relatively few examples of established practices. However, the same survey offers an informal measure of the impact of V-BID: 52 percent of senior leadership and 49 percent of all other employees felt satisfied or very satisfied with the programs in place.[2] Therefore, since the experience with V-BID is still in the early stages, it is critical that plans retain the ability to experiment and innovate and not be required to follow a single approach – especially since the returns on V-BID often accumulate after two or more years. Plans need to engage in everything from simple trial-and-error-refinement to rigorously designed pilots that allow them to evaluate lessons learned, and then redesign accordingly.

Currently available patient claims systems allow for accurate measurement of patient utilization and related cost sharing levels for designated high-value preventive services. However, it is important to note that many of these services are provided both for screening and non-screening purposes. **Thus, most of these systems are unable to account for the clinical nuance in the implementation of Section 2713 in that a recommended preventive service [e.g. cholesterol testing or colonoscopy] is commonly performed both as screening and monitoring of established disease.** While the preventive services recommendations clearly distinguish between high-risk and low-risk populations, it is more difficult for plans to segregate these populations because ICD codes do not make distinctions between preventive and non-preventive services. As a result, many of the United States Preventive Services Task Force (USPSTF) recommendations contain ambiguities that could lead to varying interpretations. For the successful implementation of Sec 2713, future iterations of ICD codes [or other billing systems] must distinguish between preventive and non-preventive use of services.

Two common-sense examples will quickly demonstrate how better understanding of a "clinically nuanced" V-BID approach will improve the clinical outcomes and efficiency of preventive services delivery as directed by the statute, but also illustrate the administrative challenge of accurately eliminating copayments only for those services and patient groups as recommended by the USPSTF.

[2] Center for Health Value Innovation. "Value-Based Design 2010: Survey Report 2011." Available at: http://www.vbhealth.org/wp-content/uploads/VBD2010-Survey-Report-FINAL-2-11-2011.pdf

- Colorectal screening with colonoscopy is an important life-saving preventive service that will be provided at no cost sharing under the preventive health provisions in PPACA because it is recommended by the USPSTF. It is important to note that the USPSTF only recommends colonoscopies for adults between the ages 50-75. The USPSTF thereby acknowledges the simple but crucial V-BID principle that the value of preventive services depends on the targeted patient population. Because the USPSTF guideline does not include individuals below the age of 50 or over the age of 75 for this preventive service, they should not be eligible for the cost sharing elimination. Thus, the V-BID approach provides a mechanism to ensure that patient cost sharing is eliminated when recommended by the USPSTF, but would allow (not force) health plans to impose patient copayments to discourage the use of services when not included in the USPSTF guideline.

- Another example of how V-BID can work to make preventive services more effective is the USPSTF recommendation for screening for Type 2 Diabetes Mellitus in adults. USPSTF guidelines are clear that not every adult needs to be screened for Type 2 diabetes. Adults with elevated blood pressure are recommended by the USPSTF to be screened, and therefore, should be screened at no cost. However, the USPSTF concludes that screening individuals with normal blood pressure would lead to increased costs with little or no clinical benefit. Using V-BID to eliminate cost sharing for diabetes screening for the adult with high blood pressure (as recommended by the USPSTF) and allowing cost sharing to discourage testing for adults at low risk for diabetes, would most effectively implement the intent of Congress to encourage clinically- and cost-effective preventive services.

As electronic medical records become more commonplace, largely because of funding made available in the American Recovery and Reinvestment Act, the ability to target clinically effective care and specific patient populations will become even greater and offer even more potential to improve patient outcomes. In addition, the creation of specific billing codes for services used only for screening purposes [e.g., screening cholesterol, screening colonoscopy], will enhance the ability to operationalize the desire of Section 2713.

Research methodologies to measure the effects of V-BID on plan costs and aggregate medical expenditures have been developed/used by the V-BID Center. These accepted approaches have been used by other researchers to assess the clinical and financial impact of V-BID in other settings.

Key evaluation components include:

- Use of appropriate control groups
- Measure patient reported clinical outcomes in addition to clinical process measures
- Incorporate long-term follow-up
- Include non-medical benefits of health improvement, such as productivity and disability

The more granular the clinical and financial outcomes measured, the more accurate assessment of the real value of the programs.

The preventive services included in Sec 2713 were recommended by panels of clinicians for use by other clinicians – these recommendations were never intended to be used for coverage purposes, since they lack the precision of language developed expressly for the purpose of providing coverage.

6. Are there particular instances in which a plan or issuer has decided not to adopt or continue a particular V-BID method? If so, what factors did they consider in reaching that decision?

In the self-insured market, we are unaware of any V-BID implementer that has not continued the program, and most have expanded. There is enormous momentum in the market toward greater adoption. A national survey conducted by Mercer in 2010 found that 81 percent of large employers plan to offer a V-BID option in the near future.[3] Another 2010 survey of 176 public, private, not-for-profit, and government employers found that of the 53 percent of employers who offered a V-BID plan, 16 percent had begun to do so in the last year, indicating that plans are expanding in a "viral" fashion.[2]

There is an unpublished report of a single V-BID program that lowered copayments for certain classes of medications with the goal of increasing medication adherence, but found that the lower copayments resulted in utilization of more expensive therapies. Our own controlled trial did not show a proportionate increase in the use of high cost drugs, but instead found that when copayments are lowered for all [generic and brand] drugs within a high-value class [e.g. hypertension, diabetes, asthma], increases in adherence are similar for both brand and generic drugs.

Although there is growing interest from employer groups and health plans in V-BID programs, there are perceived barriers to implementation. Recognition of these possible obstacles is part of the solution to overcoming them.

- Potential for short-term increase in utilization and cost. Lowering costs for targeted preventive and chronic disease services will increase short-term spending and utilization. Yet, the expectation is that better adherence will result in better health and fewer adverse complications in chronic conditions. There is a concern, however, that when copayments are reduced and costs rise, clinical status may not improve for enough of the targeted population to offset the costs associated with increased use of benefits. Available evidence would suggest that V-BID programs of more than 2 years duration would not add to aggregate medical expenditures.

- Need for sophisticated data systems to identify high-value services and the patient groups that will benefit from them. Broader data are the key to understanding opportunities and integrating V-BID into existing and emerging health information systems and disease management programs.

- Negative reactions from plan members whose copayments are higher than those of other members for the same medical service or drug. V-BID programs that target specific diagnoses or high-risk patients may encounter this problem, but clear communication of V-BID objectives can engender a positive response from employees.

- Privacy issues. The transfer of data and communications efforts must comply with the Health Insurance Portability and Accountability Act (HIPAA), a similar compliance issue arises with disease management programs.

- Quantifying clinical and economic return on investment (ROI). Although there is an ongoing debate about whether V-BID strategies produce a short-term positive ROI, expanded use of V-BID and improved adherence to beneficial therapy hold the prospect of improved health outcomes, lower costs, and healthier, more productive employees.

[3] Niteesh K. Choudhry, Meredith B. Rosenthal, Arnold Milstein. "Assessing the Evidence for Value-Based Insurance Design" Health Affairs 29: 1988-1944 (2010).

Despite these initial concerns, the V-BID Center has collected numerous testimonials from V-BID-users that these programs are very well received. As was mentioned earlier, surveys demonstrate that satisfaction is high among employees and leadership at firms that adopt V-BID.

7. What are the criteria for adopting V-BID for new or additional preventive care benefits or treatments?

Plans will consider research and evidence-based clinical guidelines in evaluating whether V-BID should be provided to a specific service and/or population. Factors in this decision may include:

- The health/access needs of the population
- Indications of research and evidence-based clinical guidelines with respect to specific treatment options
- Whether there are different incentives that may have greater success, based on recent research
- Current utilization patterns and existence of quality gaps
- Need to assure affordability

Of note, a 2011 study published in the *Annals of Family Medicine* reported that Medicare pays for certain preventive procedures that are not recommended by expert panels (such as the USPSTF) and does not cover high value preventive services that have been recommended by those same organizations (including some preventive services that are designated by Section 2713).[4]

We believe the V-BID premise of reduced patient cost sharing for high-value, evidence-based care has important implications beyond primary preventive services as mandated in Section 2713. Evidence-based secondary preventive care and chronic disease services have been a common and successful field of implementation for V-BID plans.

8. Do plans or issuers currently implement V-BIDs that have different cost sharing requirements for the same service based on population characteristics (for example, high vs. low risk populations based on evidence)?

Most well established V-BID plans concentrate on the provision of high-value pharmaceuticals, and the majority of these do not stratify by risk.

As noted earlier, more complex V-BID plans stratify by condition and the most sophisticated programs use disease severity (e.g., asthma ER users, coronary disease patients with heart attacks). Some issuers use V-BID only in concert with disease management – which usually selects patients of certain level of severity. As plans become increasingly refined in using predictive modeling to target disease management and other quality improvement programs to ever-more granular sub-populations, they may wish to target V-BID more finely.

Some V-BID programs may identify specific groups within a population for participation based on health characteristics (e.g., presence of a comorbidity) or that the individuals may need targeted incentives to encourage participation (e.g., individuals with heart disease who are not taking prescribed medications).

The promise of future V-BID programs is to be able to specifically tailor benefits based on at-risk patient populations and, ultimately, individual characteristics. Until then, however, we must again emphasize that

[4] Lenard I. Lesser, Alex H. Krist, Douglas B. Kamerow, Andrew W. Bazemore. "Comparison Between US Preventive Services Task Force Recommendations and Medicare Coverage." Annals of Family Medicine 9:44-49 (2011).

the goal of V-BID is to provide clinically appropriate preventive and chronic disease care for at-risk individuals. In these circumstances, those identified as being at-risk would be targeted with incentives to seek appropriate care, rather than the status quo where barriers exist that lead to lower adherence with recommended services, which in most circumstances leads to worse clinical outcomes and possibly higher total costs.

9. What would be the data requirements and other administrative costs associated with implementing V-BIDs based on population characteristics across a wide range of preventive services?

As with any health plan intervention, V-BID programs are frequently monitored by internal health plan or academic research to determine what is clinically effective.[5] A critical data point needed to assess the cost of a V-BID program is real-time information on gaps in high-value care.

Comprehensive administration of V-BID programs requires technology and expertise to automate and analyze data, but the requirements for each program vary depending on the specific population, medical condition, and program design features. Understanding the importance of clinical context, a health plan or issuer may utilize the following capabilities:

- Analytics to support V-BID program design, member identification, member program compliance and V-BID program effectiveness:
- A database containing medical and pharmacy claims, health assessment data, biometrics from physicians or worksite collection
- Analysis of risk factors and illness burden of population to drive appropriate V-BID areas of focus
- Identify members for specific programs
    - Ongoing analysis of member compliance with V-BID program to earn enhanced benefits, other rewards
    - Compliance for participation in programs or for outcomes
    - Analysis of program effect on member risk scores, ER/hospital use, medical cost trend, medication adherence, absenteeism
    - Compare members without V-BID to those with it
- Tools to establish multiple V-BID programs to offer to employers:
    - Healthy Living/Preventive V-BID
    - Chronic Condition Management V-BID
    - Member actions required in programs
- Use specific providers or settings
- Deposit funds in HRA for V-BID rewards
- Employers and their payroll systems to provide reduced member premium contributions

Many of these capabilities have already been funded for development in the Patient Protection and Affordable Care Act, and where additions are necessary they should not be overly costly. **It should be explicitly stated that V-BID programs should not be subject to clinical-monitoring requirements above and beyond what is required for other plan designs.**

[5] For example, the entire November 2010 issue of Health Affairs focused on research surrounding V-BID and its effectiveness in various interventions. (Available at: http://content.healthaffairs.org/content/29/11.toc)

Finally, as noted above, current ICD codes do not make distinctions between preventive and non-preventive treatments. For the goals of Sec. 2713 to be attained, indication-specific coding systems that denote that a service was used for prevention/screening (rather than treatment/monitoring) are essential.

10. What mechanisms and/or safety valves, if any, do plans and issuers put in place or what data are used to ensure that patients with particular co-morbidities or special circumstances, such as risk factors or the accessibility of services, receive the medically appropriate level of care?

> **a) For example, to the extent a low-cost alternative treatment is reasonable for some or the majority of patients, what happens to the minority of patients for whom a higher-cost service may be the only medically appropriate one?**

Plans must take into account the needs of individuals when designing V-BID programs such that special clinical circumstances will be dealt with fairly. It is commonplace for a plan to determine that certain members with a chronic or a prolonged illness would benefit from complex case management or a highly specialized disease management program. However, **the greatest safety mechanism for patients who participate in V-BID programs is the clinical nuance upon which the determination of what is high-value is based.** As V-BID aims to remove barriers to essential, high-value services, the more clinical evidence that is used by plans, the more patients will be targeted with the correct clinical intervention. For instance, recent research has shown that providers insert coronary stents in patients where it has no additional clinical benefit (and may actually cause harm) beyond much less expensive and less invasive prescription drugs. However, in patients with different clinical circumstances [e.g., acute myocardial infarction], these same stents can be extremely high-value. The more clinically nuanced the plan design, the more it can appropriately target incentives to the individual patient. Since there are instances where a higher-cost service may be appropriate, we recommend giving plans the flexibility to provide incentives for these selected individuals to take advantage of such alternative approaches.

Our Center works to monitor the implementation of V-BID programs around the country and we have worked to ensure that V-BID plans are distinguished by the inclusion of clinical elements. Certain benefit designs reduce barriers to certain health care services based entirely on purchase price. **We strongly believe that programs that do not include a clinical component fail to meet the V-BID definition.** For example, a program that reduces or eliminates cost sharing for all generic drugs or all cancer screenings – regardless of the clinical benefit provided – should not meet the definition of V-BID, because it fails to explicitly address the clinical benefit achieved with clinically nuanced changes in patient cost sharing.

The fact that patient cost sharing is prohibited for only certain recommended preventive services and for certain patient populations – based on their clinical merit - makes Section 2713 an ideal statute for demonstrating the value of V-BID.

11. What other factors, such as ensuring adequate access to preventive services, are considered as part of a plan or issuer's V-BID strategy?

It is our belief that a well-designed V-BID program will remove barriers and incorporate necessary incentives/plan elements to ensure that patients receive high-value preventive/chronic disease care in the appropriate setting. State laws set network adequacy requirements where plans must demonstrate that they have adequate access to all specialties of care.

Many plans tie V-BID programs to wellness initiatives and existing disease management programs to increase the efficacy of all offerings. From the perspective of plan issuers, V-BID programs also increase individual accountability for dealing with expensive, chronic diseases. **V-BID plans can also act as follow-on to a preventive care regimen, ensuring that individuals identified during preventive screenings have access to effective therapies.** V-BID plans can also offer ongoing feedback to ensure that quality metrics are met. Finally, V-BID allows plans to manage other important conditions separate from preventive services.

12. How are consumers informed about V-BID features in their health coverage?

Communicating with V-BID program participants is clearly important to creating a valuable program for plans and issuers as well as patients. Goals and requirements must be culturally appropriate and understood in order for full participation to occur and the benefits of better health, lower costs, or both, to accrue.

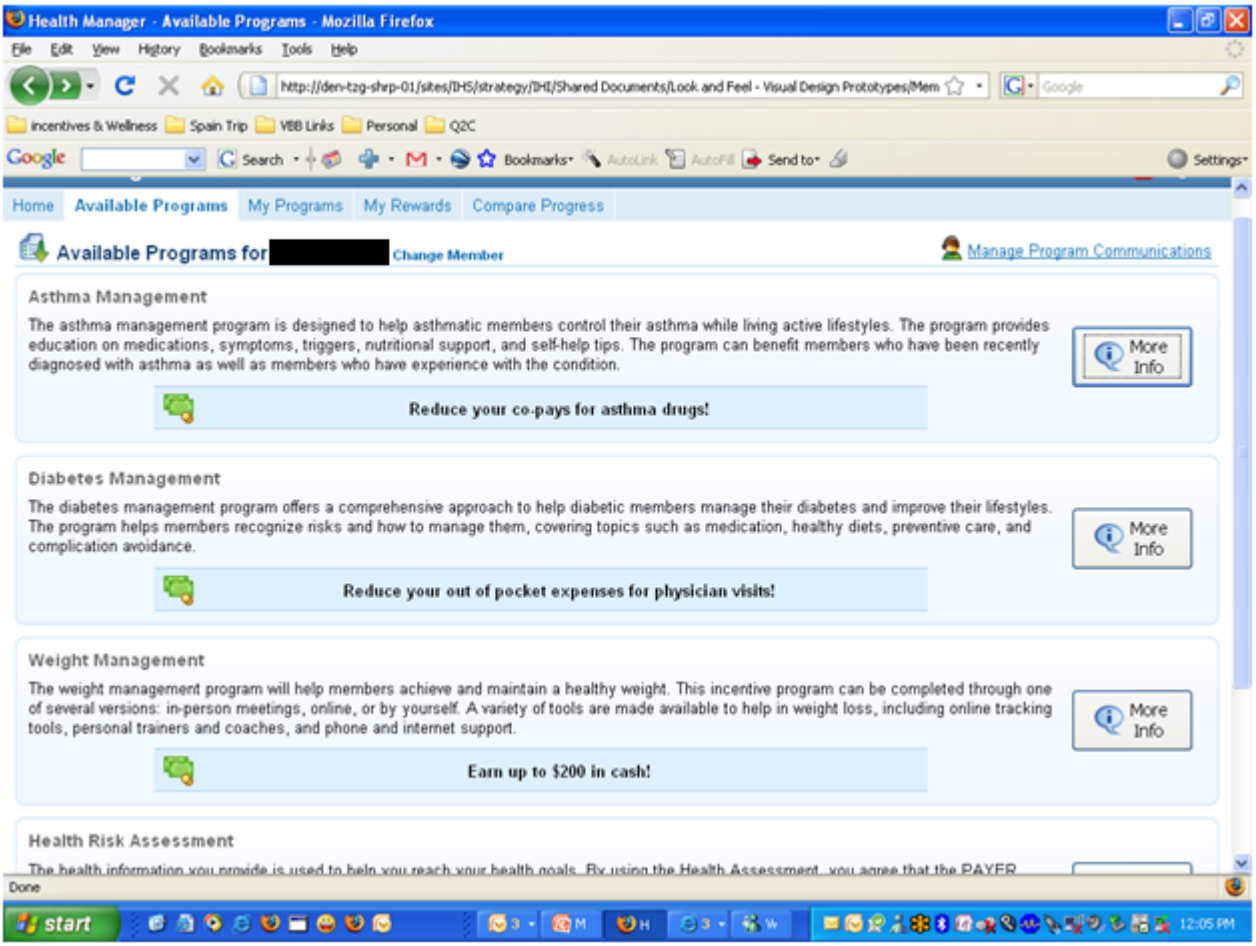
Participants often receive information regarding:

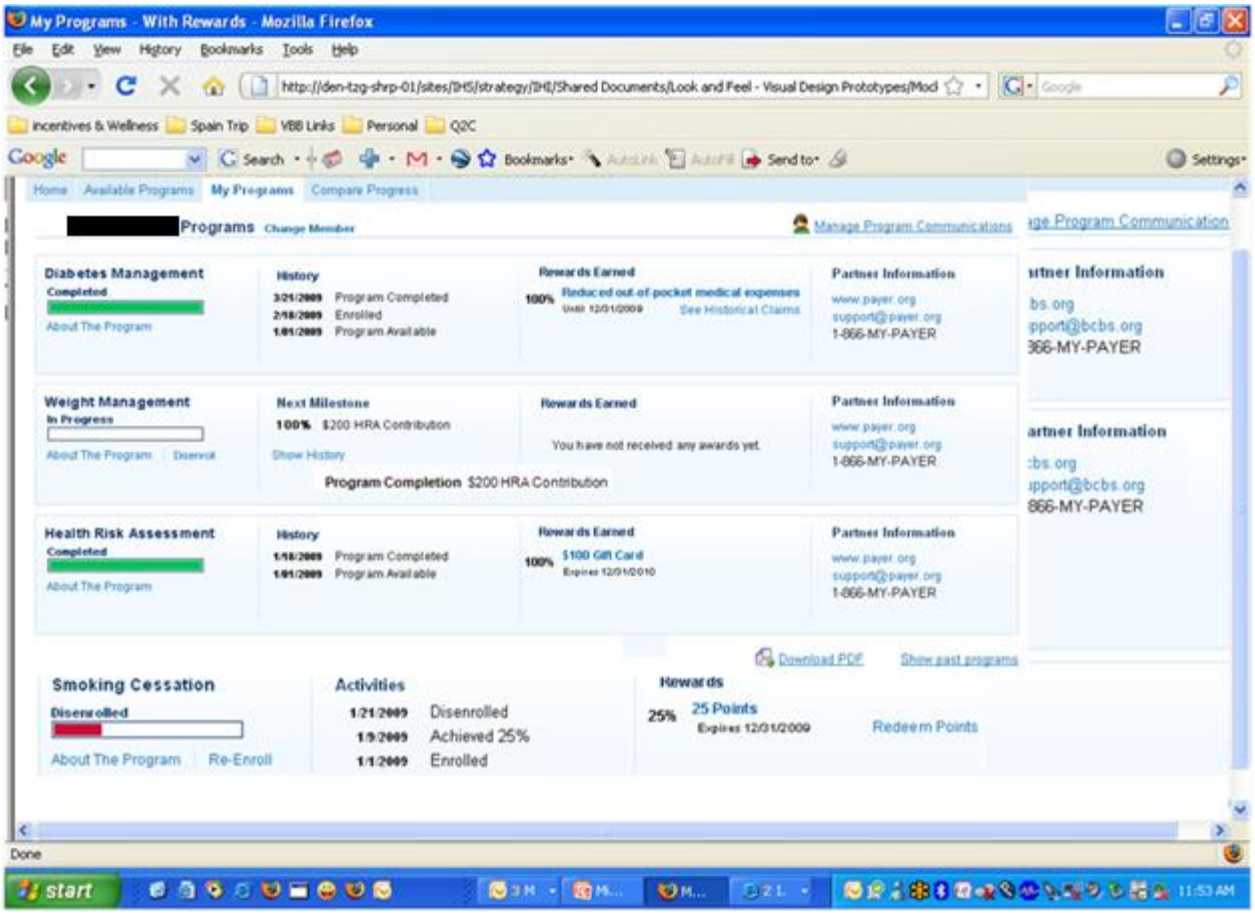
- State and federal required "explanation of coverage" (EOC) and "standard plan document" information provided to prospective enrollees and on enrollment in coverage
- Publication of information about programs targeted to specific populations through plan newsletters, websites, phone calls to members, and other media
- Working with employers to distribute information to employees and their family members
- Providing information to physicians and other treating health care providers to share with their patients

The format in which participants receive this information may include e-mails, newsletters, employer websites, special workshops, programs or meetings, posters in the workplace, podcasts, or text messages. The most popular method of communication is e-mail, and a 60 percent majority of employers communicate either monthly or quarterly.[6]

An example of online member communications for V-BID programs is the following member website view which gives members the ability to see which programs are available to them and to track their status in programs:

[6] Center for Health Value Innovation. "Value-Based Design 2010: Survey Report 2011." Available at: http://www.vbhealth.org/wp-content/uploads/VBD2010-Survey-Report-FINAL-2-11-2011.pdf


Health Manager - Available Programs - Mozilla Firefox
File Edit View History Bookmarks Tools Help
http://den-tzg-shrp-01/sites/IHS/strategy/IHI/Shared Documents/Look and Feel - Visual Design Prototypes/Mem
incentives & Wellness Spain Trip VBB Links Personal Q2C
Google Search Bookmarks AutoLink AutoFill Send to Settings
Home Available Programs My Programs My Rewards Compare Progress
Available Programs for [redacted] Change Member
Manage Program Communications
Asthma Management
The asthma management program is designed to help asthmatic members control their asthma while living active lifestyles. The program provides education on medications, symptoms, triggers, nutritional support, and self-help tips. The program can benefit members who have been recently diagnosed with asthma as well as members who have experience with the condition.
More Info
Reduce your co-pays for asthma drugs!
Diabetes Management
The diabetes management program offers a comprehensive approach to help diabetic members manage their diabetes and improve their lifestyles. The program helps members recognize risks and how to manage them, covering topics such as medication, healthy diets, preventive care, and complication avoidance.
More Info
Reduce your out of pocket expenses for physician visits!
Weight Management
The weight management program will help members achieve and maintain a healthy weight. This incentive program can be completed through one of several versions: in-person meetings, online, or by yourself. A variety of tools are made available to help in weight loss, including online tracking tools, personal trainers and coaches, and phone and internet support.
More Info
Earn up to $200 in cash!
Health Risk Assessment
Done
start
12:05 PM



13. How are prescribing physicians/other network providers informed of V-BID features and/or encouraged to steer patients to value based services and settings?

With regard to informing clinicians about services offered through V-BID programs, plans can communicate the availability of services included in a V-BID program through a wide variety of methods:

- Notification of member eligibility
- Continuing Medical Education
- Reminder systems for gaps in care
- Promotion of coverage and health plan offerings
- Codes for reimbursement
- Incentives for conducting screening
- Incentives for program referral (education about a plan-sponsored smoking cessation program)
- Pay for performance programs
- Newsletters
- Fax blast bulletins or mailed bulletins
- E-alert communications or bulletins
- Administrative manuals/tool kits
- Web site provider portals

As electronic health records become more pervasive as a result of the funding made available in the American Recovery and Reinvestment Act, the ability to provide real-time information to providers on V-BID features should become relatively commonplace. Additionally, the development of Accountable Care Organizations (ACOs) will itself help organize providers into more high-value, coordinated teams of care where V-BID networks and benefits will be built into the ACO itself.

Regarding setting of care, the Department of Labor emphasized this distinction in a clarification of the Affordable Care Act it issued in November 2010. In a "Frequently Asked Questions" publication,[7] the Department advised that under the Affordable Care Act, plans are permitted to use "reasonable medical management techniques" to steer patients toward lower-cost settings of care for preventive services, as long as the care provided in these settings is medically appropriate.

14. What consumer protections, if any, need to be in place to ensure adequate access to preventive care without cost sharing, as required under PHS Act section 2713?

We appreciate the Department's appropriate concern for ensuring adequate access to preventive care, and we believe that current regulations provide adequate protections. From a consumer perspective, information about preventive care without cost sharing, as required under PPACA Section 2713, needs to be clearly presented in a culturally sensitive manner. From the payer perspective, plans must provide access to preventive care at no cost sharing in accordance with Section 2713 or they face significant penalties of up to $100 per day for each individual affected under the Public Health Service Act. **As we have emphasized, V-BID programs serve to facilitate access to treatments and services, not to impose barriers to care.**

Section 2713 embodies the definition of Value-Based Insurance Design as it lowers barriers to those services with proven clinical effectiveness (as recommended by the USPSTF). Adherence to this definition balances broader access with potential for lower overall costs, using clinical nuance to improve health outcomes. V-BID's success to date has depended in no small part on the ability of private and public health plans and self-insured companies to innovate with clinicians, health systems and patient advocates. *Preserving flexibility to innovate, experiment, and evaluate is important to the future of V-BID.*

[7] For more information, see http://www.dol.gov/ebsa/faqs/faq-aca5.html