



September 17, 2010

Submitted electronically via the Federal Rulemaking portal @ www.regulations.gov

Attention: OCIO-9992-IFC
Department of Health and Human Services
Office of Consumer Information and Insurance Oversight
P.O. Box 8016
Baltimore, Maryland 21244-1850

Re: Comments to Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act

CENTER FOR VALUE-BASED INSURANCE DESIGN:

The University of Michigan Center for Value-Based Insurance Design was established in 2005 to develop, evaluate, and promote value-based insurance initiatives in order 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.

OVERVIEW OF VALUE-BASED INSURANCE DESIGN:

Value-Based Insurance Design (V-BID) is one of the most innovative and widely implemented approaches to enhance clinical outcomes and control the cost of health care. A broad and diverse coalition of health care and business leaders across the country, as well as political leaders from across party aisles, support expanded utilization of V-BID programs to simultaneously address quality improvement and cost containment, both for preventive care and the management of chronic medical conditions. The Medicare Payment Advisory Commission (MedPAC) advocated exploring V-BID as a way to improve Medicare and control its cost-growth,¹ and a bipartisan group of health policy experts organized by the Brookings Institution included V-BID as a recommendation to “bend the cost-curve” in health care reform.²

¹ Medicare Payment Advisory Commission, “Improving Incentives in the Medicare System,” Report to Congress 2009, 2010.

² Brookings Institution, “Bending the cost-curve: Effective Steps to Address Long-Term Health Care Spending Growth,” September, 2009. Available at: http://www.brookings.edu/reports/2009/0901_btc.aspx#

The goal of V-BID is to structure health plan design elements to optimize patient health through increased utilization of evidence-based health care services. In particular, V-BID lowers financial barriers to high-value services and provides disincentives for low-value care. Restructuring health insurance plans to provide patient incentives for evidence-based care can help refocus the health care system on quality outcomes rather than volume, especially if the provider payment system is restructured along similar lines.

As indicated by the Interim Final Rules (IFR), Section 2713 (c) of the Patient Protection and Affordable Care Act (PPACA) provides the Secretary of Health and Human Services (HHS) with authority to propose guidelines allowing employers and health insurers to utilize V-BID in providing preventive health services. This language recognizes that properly structured V-BID programs provide more clinically effective health care, prevent chronic disease, and promote better health. We are delighted that the IFR will allow employers and insurers to utilize V-BID when implementing the preventive health provisions of federal health care reform. We believe these rules will ensure the appropriate utilization of evidence-based preventive health services.

1. WE SUPPORT THE DEFINITION OF VALUE-BASED INSURANCE DESIGN IN THE IFR AND BELIEVE IT REPRESENTS THE INTENT OF CONGRESS:

We affirm the definition of value-based insurance design as written on page 41729 of the IFR:

“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.”

CONGRESSIONAL SUPPORT FOR V-BID IN FEDERAL HEALTH CARE REFORM:

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. Senators Stabenow (D-MI) and Hutchison (R-TX) introduced legislation promoting the use of V-BID in Medicare (S. 1040), and as part of the Senate Finance Committee’s consideration of health care reform, Chairman Baucus (D-MT) included V-BID in the Chairman’s Mark of the bill. In the Chairman’s Mark, V-BID was defined as “A methodology for identifying clinically beneficial screenings, lifestyle interventions, medications, immunizations, diagnostic tests and procedures, and treatments for which co-payments or coinsurance should be adjusted or eliminated due to their high value and effectiveness when prescribed for particular clinical conditions.” Similar language remained in the Senate bill. Language incorporating V-BID principles was also included in H.R. 3962, the House version of legislation that combined the efforts of three committees and passed on November 7, 2009.³

³ Section 324(c) of the legislation would have allowed health benefits plans to modify cost-sharing and payment rates to encourage the use of services that promote health and value.

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

Sec. 2713 of PPACA provides that certain recommended preventive care services must be provided without patient cost sharing. These services include: 1) those receiving an A or B rating from the United States Preventive Services Taskforce (USPSTF), 2) immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, 3) for infants, children and adolescents, preventive care and screenings supported by the Health Resources Administration (HRSA), 4) for women, any additional preventive care and screenings recommended by HRSA. **The prohibition of patient cost-sharing for selected evidence-based screenings and preventive care for specified populations of children, adolescents, and adults is entirely consistent with core V-BID principles: 1] health care services differ in the health benefits they produce; 2] we should promote the use of clinically effective care, 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.

IMPORTANCE OF CLINICAL NUANCE IN THE IMPLEMENTATION OF SECTION 2713:

Two common-sense examples will quickly demonstrate how incorporation of a “clinically nuanced” V-BID approach will improve the clinical outcomes and efficiency of preventive services delivery as directed by the statute:

- 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.⁴ It is important to note that the USPSTF only recommends colonoscopies for adults between the ages 50-75.⁵ 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.

⁴ Recommendations of the U.S. Preventive Services Task Force, Guide to Clinical Preventive Services, 2009. Available at: <http://www.ahrq.gov/clinic/pocketgd.htm>

⁵ Specifically, the USPSTF recommends colonoscopies for “Adults aged 50-75 using fecal occult blood testing, sigmoidoscopy, or colonoscopy.” Recommendations of the U.S. Preventive Services Task Force, Guide to Clinical Preventive Services, 2009.

- 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.⁶ 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.

Regulations on preventive care should allow employers and insurers to adjust cost-sharing for required preventive services based on evidence-based guidelines. These regulations would support the intent of Congress by prohibiting cost-sharing for any preventive care recommended under guidelines established by the USPSTF, HRSA, or the CDC, while allowing cost-sharing for those same services if not clinically recommended by these organizations. This clinically nuanced approach would alleviate a significant amount of uncertainty surrounding the new preventive care requirement. **Guidance that allows for V-BID to be used in this matter would provide much-needed clarity on this important issue, and ensure that preventive care resources are focused where most clinically effective.**⁷

BENEFIT DESIGNS THAT ARE NOT V-BID:

The inclusion of clinical elements is essential to meet the definition of V-BID. 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 in the setting of patient cost-sharing. **The fact that patient cost-sharing is prohibited for only certain preventive services and for certain patient**

⁶ The USPSTF recommends this screening for “asymptomatic adults with sustained blood pressure greater than 135/80 mg Hg.” Recommendations of the U.S. Preventive Services Task Force, Guide to Clinical Preventive Services, 2009.

⁷ Plans and employers could be limited on the amount they could vary co-payments where not clinically indicated so that they were no more than the average co-payment, or no more than under the plan prior to implementation of the change.

populations – based on their clinical merit - makes Section 2713 an ideal statute for demonstrating the value of V-BID.

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

While we applaud the language in the pending IFR on preventive services, we believe **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 on primary prevention. Evidence-based services for those with identified chronic diseases such as eye examinations for those with diabetes, behavioral therapy for individuals with depression, and long-acting inhalers for asthma sufferers offer as much or more value than those preventive services identified in Section 2713. These services – often referred to as “secondary prevention” - are typically the foundation of quality improvement programs, such as pay for performance, disease/condition management and health plan accreditation. While we recognize that regulatory bodies cannot specify all high-value services, breadth in defining value as an outcome of measure improvement in quality care is an important consideration. **A provision to allow the identification of high-value secondary prevention services that would be made available without patient cost-sharing, similar to those primary prevention services selected in Section 2713, would be an important extension of the health enhancing and cost containment goals of PPACA.**

The academic evidence is very clear that charging high copayments or deductibles for evidence-based services reduces their use, leads to lower quality of care and potentially higher costs. This finding is consistent across all types of services including ambulatory office visits, mammograms, important medications for managing chronic disease and other quality metrics.⁸ Equally troublesome is that the impact of high levels of patient cost-sharing is concentrated on low-income populations, supporting the view that high copayments exacerbate health disparities.⁹ Value-based insurance design, through lowering copayments for such high-value services, is demonstrated to improve quality without increasing aggregate medical expenditures and can be judiciously installed to

⁸ Trivedi AN, Moloo H, Mor V. Increased ambulatory care copayments and hospitalizations among the elderly. *N Engl J Med* 2010;362:320-328. Trivedi AN, Rakowski W, Ayanian JZ. Effect of cost-sharing on screening mammography in Medicare Health Plans. *New England Journal of Medicine*. 2008;358(4):375-383. Goldman DP, Joyce GF, Zheng Y. Prescription Drug Cost Sharing. Associations with Medical Utilization and Spending and Health. *The Journal of the American Medical Association*. 2007;298(1):61-27. Chernew ME, Gibson TB. Cost Sharing and HEDIS Performance. *Medical Care Research and Review*. 2008; 65(6):713-729.

⁹ Chernew ME, Gibson TB, Yu-Isenberg K, Sokol MC, Rosen AB, Fendrick AM. Effects of Increased Patient Cost Sharing on Socioeconomic Disparities in Health Care. *J Gen Intern Med* 2008 23(8):1131–6.

accommodate varying socio-economic issues.¹⁰ Expanding the United States Preventive Services Taskforce (its current mandate is limited to primary prevention) or the establishment of an analogous entity to identify high-value secondary prevention services eligible for reduced levels of patient cost sharing, would have a substantial and immediate impact from both a clinical and financial perspective, due to the large differential in expenditures on primary and secondary preventive services by both private and public payers.

The ultimate test of health reform will be whether it expands coverage in a way that improves health and addresses rapidly rising costs. V-BID offers one of the simplest yet most promising opportunities to encourage clinically-effective care by creating the incentive for Americans to get the preventive care they need in a way that can lower overall health care cost trends while improving total health outcomes. Congress included language to authorize V-BID in every step of the legislative process, and it is important that the Departments complete this work by implementing regulations that will allow V-BID to move forward as part of the implementation of health reform.

Our multidisciplinary team of University of Michigan researchers introduced the concept of Value-Based Insurance Design over a decade ago. We have worked with hundreds of 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 the Departments develop further guidance advancing this important innovation in benefit design.

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

Sincerely,



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cc: Peter Lee, Office of Health Reform, Department of Health and Human Services
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¹⁰ Chernew ME, Shah MR, Wegh A, Rosenberg SN, Juster IA, Rosen AB, Sokol MC, Yu-Isenberg K, Fendrick AM. Impact Of Decreasing Copayments On Medication Adherence Within A Disease Management Environment. *Health Affairs*, 2008: 27; 103-112.