



September 30, 2011

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

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9992-IFC2,
P.O. Box 8010,
Baltimore, MD 21244-8010

Re: Comments on Amendments to the Interim Final Regulations Implementing the Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under 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 In March, 2011, V-BID was also highlighted in the National Quality Strategy.³

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

² Brookings Institution, “Bending the Curve through Health Reform Implementation,” October, 2010. Available at: <http://www.sph.umich.edu/vbidcenter/publications/pdfs/BrookingsBendingtheCurve102010.pdf>

³ Please see: <http://www.healthcare.gov/law/resources/reports/quality03212011a.html>

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.

COMMENTS ON THE AMENDMENT

Since the IFR was implemented in September, 2010, we believe the rules governing Section 2713 have better enabled the appropriate utilization of evidence-based preventive health services. In comments submitted at that time, we signaled our support for three key aspects of the regulation:

1. **WE SUPPORT THE DEFINITION OF VALUE-BASED INSURANCE DESIGN IN THE IFR AND BELIEVE IT REPRESENTS 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;**
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.**

We continue to believe that the IFR is a faithful interpretation of Congress's will that will improve uptake of needed preventive services. This amendment to the IFR will extend to women preventive services that have been studied and recommended by the Institute of Medicine, including FDA-approved contraceptives, HPV testing, screening for gestational diabetes, sexually transmitted infection counseling, HIV screening and counseling, lactation support and counseling, screening and counseling for domestic and interpersonal violence, and at least one annual well-woman preventive care visit.⁴ **We commend the Departments for extending the regulations to provide access to these clinically proven services without cost sharing, as prescribed in the law and recommended by the Institute of Medicine.** As barriers to effective and needed services fall, the nation's health will improve.

⁴ Institute of Medicine, "Recommendations for Preventive Services for Women that Should be Considered by HHS." Available at: <http://iom.edu/Reports/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps/Recommendations.aspx>

At the same time, we continue to 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.⁵ 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.⁶ 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 accommodate varying socio-economic issues.⁷ 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.

⁵ 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.

⁶ 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.

⁷ 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.

Expanding coverage in a way that improves health and addresses rapidly rising costs continues to be the central challenge in health reform. 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.

CONCLUSIONS

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,

A handwritten signature in dark ink, appearing to read 'A. Mark Fendrick', is displayed on a light gray rectangular background.

A. Mark Fendrick, MD
Professor of Internal Medicine and Health Management & Policy
Director, Center for Value-Based Insurance Design
University of Michigan