



February 28, 2011

By Electronic Mail

The Honorable Timothy Geithner  
Secretary, U.S. Department of Treasury

The Honorable Kathleen Sebelius  
Secretary, U.S. Department of Health and Human Services

The Honorable Hilda Solis  
Secretary, U.S. Department of Labor

**Re: Comments on the “Request for Information” Regarding Value-Based Insurance Design in Connection With Preventive Care Benefits (HHS-OS-2010-002)**

Dear Mr. and Mmes. Secretary:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments in response to the “request for information” (HHS-OS-2010-002) regarding value-based insurance design in connection with preventive care benefits, as provided for under Section 2713 of the Patient Protection and Affordable Care Act (P.L. 111-148) and the Health Care and Education Reconciliation Act (P.L. 111-152), jointly referred to as the Affordable Care Act (ACA). PhRMA is a voluntary, non-profit organization representing the nation’s leading research-based pharmaceutical and biotechnology companies who are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.

Section 2713 of the ACA requires group health plans and health insurers to provide coverage for specified preventive care services without any cost-sharing. Section 2713 also provides that: “The [HHS] Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance design.”<sup>1</sup> PhRMA supports private sector efforts that seek to improve the quality of care for patients with chronic conditions—including programs that enhance access to preventive care, promote better coordination of care, and improve care and medication compliance through reducing or eliminating cost-sharing for medications and other services. These programs, often referred to as value-based or clinically-sensitive benefit designs, have been offered by major private employers, health plans, and state governments, and are

---

*Pharmaceutical Research and Manufacturers of America*

950 F Street, NW, Washington, DC 20004 • Tel: 202-835-3400



focused on better meeting the needs of individuals with chronic conditions who may be poorly served by benefit designs which offer better financial protection for acute health care needs than for ongoing, chronic care. Such programs typically reduce cost sharing for prescription medicines and other services related to slowing the progression of chronic conditions, and so include a broader range of services than those which must be offered without cost sharing as required by Section 2713.

Early evidence from these innovative approaches to clinically-sensitive benefit design show that programs which reduce cost sharing for prescription medicines offer significant potential to improve medication adherence, quality of care and clinical outcomes for patients. For example:

- Pitney Bowes reduced cost-sharing for prescription drugs to treat diabetes, hypertension and asthma as part of a comprehensive disease management program. The result was greater patient adherence to medications as well as reductions in medical costs.<sup>2</sup>
- A similar program that eliminated co-payments for cholesterol lowering statins and reduced them for other medications found that it improved adherence to statins by 2.6 percent and stabilized adherence for other medications.<sup>3</sup>
- A program which reduced patient cost-sharing for diabetes patients along with providing disease management services found promising results as use of medicines and adherence to diabetes medical guidelines increased.<sup>4</sup> As a result, the program produced a return on investment of \$1.33 for every dollar spent, through savings in diabetes-related medical costs.

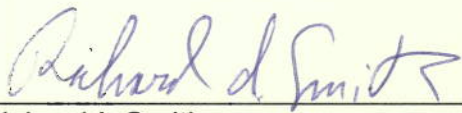
Value-based, clinically sensitive benefit designs are not ideally accomplished in a centralized fashion at the federal level, due to the early stage of development of these programs and considerable knowledge gaps about what works well under particular circumstances. At the same time, however, we recognize the role accorded by the statute to HHS in developing standards for essential health benefits and for value-based insurance programs, and recommend that the following principles guide rulemaking:

- Benefit designs that adopt lower or higher cost sharing for certain clinical services should be based on rigorous evidence.
- Benefit designs should aim to improve clinical outcomes using consensus-based measures of quality care.
- A robust and transparent process should be used to determine which benefits are “preferred” in such programs—including appropriate processes for notifying enrollees and providers about the incentives the benefit seeks to create.
- Benefits should assure patients and providers have effective access to broad choice of therapeutic options to meet patients’ specific needs.
- The value of VBID programs should not be determined solely on the basis of any short term financial returns to the payer. Instead, value should be measured and defined more broadly to reflect value to the consumer and the health care system over time.

Such protections are important to assure that innovations in cost-sharing are patient-centered and fully recognize the need to improve quality of care and health outcomes. In the absence of such protections, there is a risk that benefit designs may result in shifting costs to patients with serious illnesses, rather than promoting high-value, clinically sensitive care.

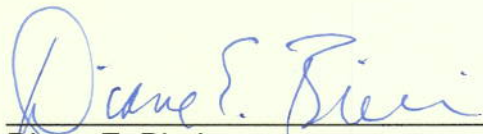
We appreciate your consideration of our comments. Please feel free to contact us with any questions.

Sincerely,



---

Richard I. Smith  
Senior Vice President, Policy and Research



---

Diane E. Bieri  
Executive Vice President and General Counsel

---

<sup>1</sup> Section 2713(c) of the Patient Protection and Affordable Care Act (P.L. 111-148).

<sup>2</sup> Mahoney JJ. Value-based benefit design: Using a Predictive Modeling Approach to Improve Compliance. *J. Managed Care Pharmacy*. 2008; 14(6 Suppl B): 3-8.

<sup>3</sup> Niteesh K. Choudry et al. "At Pitney Bowes, Value-Based Insurance Design Cut Copayments and Increased Drug Adherence." *Health Affairs*, 29, no. 11 (2010); 1995-2011.

<sup>4</sup> Teresa Gibson et al. "Value-Based Insurance Plus Disease Management Increased Medication Use and Produced Savings." *Health Affairs*, 30, no.1 (2011): 100-108.