February 28, 2011

The Honorable Phyllis C. Borzi  
Assistant Secretary, Employee Benefits Security Administration  
Department of Labor

Steve Larsen  
Deputy Administrator and Director, Center for Consumer Information and Insurance Oversight  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services

Nancy J. Marks  
Division Counsel/Associate Chief Counsel  
Internal Revenue Service  
Department of the Treasury

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

Dear Secretary Borzi, Deputy Administrator Larsen, and Counsel Marks:

Blue Shield of California appreciates the opportunity to submit this response to the “Request for Information Regarding Value-Based Insurance Design (VBID) in Connection With Preventive Care Benefits” as issued on December 28, 2010 (75 Fed. Reg. 81544). Founded in 1939, Blue Shield of California is a not-for-profit health plan with a deep commitment to expanding access to quality health care at a reasonable price for all Californians. We have roughly 3.4 million members and one of the largest provider networks in California. Over the past five years, we have donated more than $160 million to the Blue Shield of California Foundation—which was named one of Business Week’s 20 most generous corporate foundations. Blue Shield of California has a strong track record of leadership in the health reform movement. Blue Shield is committed to implementing health care reform, and will continue to work to ensure that every American has coverage and to make that coverage more affordable.

VBID provides condition-based enhanced benefits that reduce cost-sharing to encourage individuals to get high-value care in the appropriate setting. Blue Shield of California offers VBID designs that have been demonstrated to improve medication adherence among enrollees with chronic disease—which improves health outcomes and may ultimately lower costs. As discussed in our comments, Blue Shield also has a
commitment with CalPERS, the nation’s largest non-federal purchaser of health benefits, to improve the delivery of care in the appropriate setting in a way that will reduce cost trends—without shifting costs to the members. This partnership has included utilizing clinical evidence to support VBID incentives in a way that we believe could represent a model for similar determinations.

The Patient Protection and Affordable Care Act promoted many important mechanisms to help bend the cost curve in health care, including VBID. We believe VBID is one of the more promising areas for potential innovation. As VBID programs become more refined and sophisticated, they may lead to significant gains in worker productivity and lower cost trends for health insurance. We therefore would request that as the Departments approach potential future regulations, they keep in mind the need to promote innovation in this area and to encourage the development of programs that may prove central to bending the long-term health care cost curve.

Responses to Request for Information

Request for Information

A. Comments Regarding Regulatory Guidance

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

   - How is effective defined?

Response: The plan incentives that Blue Shield of California believes are in the scope of “value-based insurance design” (VBID) reduce cost-sharing to encourage individuals to get high-value care in the appropriate setting. VBID at its core provides condition-based enhanced benefits.

A key strategy of the Blue Shield approach to VBID is to remove barriers to treatments that have proven value in improving medical outcomes. As pharmacy copayments may be a potential barrier to medication adherence, our VBID benefit reduces copayments for selected medications for chronic conditions such as diabetes and asthma. Our client experience suggests a reduction in copayment can lead to approximately 6-7% improvement in medication compliance, as measured by the number of members with medication possession ratios of greater than 80%. Evidence demonstrates that increased utilization of these medications in at-risk populations can improve health and, over the long-term, may produce cost savings.

Additionally, network designs are often used to encourage individuals to utilize certain providers. However, not all network designs are VBID related. For example, PPOs will have in-network and out-of-network providers. This is a standard insurance design but
not a VBID incentive. As more data on the quality of providers becomes available, we believe it will be important to allow plans to create incentives for individuals to use high-value providers. For example, the Blue Cross and Blue Shield Blue Distinction program designates certain facilities as meeting evidence-based, objective criteria that are established in collaboration with recommendations from expert physicians and medical organizations. In addition, Blue Shield offers CalPERS enrollees a high-value HMO network of providers who meet both quality and cost efficiency thresholds. These enrollees pay lower premiums even though their benefits are exactly the same. Value-based network design features should be encouraged to provide cost-sharing incentives for members to seek care from providers that demonstrate evidence-based clinical proficiency.

The primary consideration regarding what tools are “effective” is whether they increase the uptake of clinically appropriate, evidence-based care.

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 or scans)?

Response: VBID programs are diverse and can target both conditions and treatments in preventive or non-preventive settings. For example, as stated above, Blue Shield offers a VBID pharmacy benefit that will lower co-payments for asthma medications. This would not be a preventive service as designated by the U.S. Preventive Services Taskforce. Blue Shield of California has also worked with CalPERS (as described in detail below) to provide colonoscopy screenings at no cost-sharing in ambulatory surgery centers where they are clinically appropriate and most cost-effective. Colonoscopy screenings would be considered a preventive service as designated by the USPSTF.

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

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

Response: The determination of what is high-value is complex but is always based on clinical evidence and driving towards improving the quality of care delivered. The determination should be transparent and data driven, but innovation in this area must be permitted and encouraged. An example from CalPERS, the nation’s largest non-federal purchaser of health benefits, is very instructive on this issue. Blue Shield has a
commitment with CalPERS to improve the delivery of care in the appropriate setting in a way that will reduce cost trends—without shifting costs to the members.

Late last year in response to the preventive services regulations, CalPERS requested clarification that it be allowed to impose a differential co-pay on colonoscopy screenings based on the setting of care. Specifically, CalPERS had initiated a value-based design benefit change before the preventive care requirements in PHS Act Section 2713 took effect. The benefit provided no cost-sharing for colorectal cancer screenings if done in an in-network ambulatory surgery center (ASC). However, a $250 co-pay was required if the same service was performed in an in-network outpatient hospital setting.

CalPERS modified this benefit after its February 2010 population Health Study showed that colonoscopies performed in outpatient hospital settings were 2.5 to 3 times more expensive than the same procedure performed in an ASC without equating to superior care or higher quality. CalPERS noted extensive academic literature showing no negative impact on quality or safety related to the setting of care for colonoscopies. Working with Blue Shield, CalPERS also reviewed access to colonoscopies at ASCs and concluded there was “no evidence that there are any issues related to access for these services.” Furthermore, CalPERS noted that California’s insurance regulator “heavily regulates California HMOs to ensure access.” We have attached a copy of this letter to this RFI because we believe it represents a model as to how clinical evidence should be used to support a VBID benefit.

The Department of Labor (DOL) reviewed the comments from CalPERS and determined that this benefit design would be permitted. Specifically, DOL wrote that, “Plans may use reasonable medical management techniques to steer patients towards a particular high-value setting such as an ambulatory care setting for providing preventive care services, provided the plan accommodates any individuals for whom it would be medically inappropriate to have the preventive service provided in the ambulatory setting (as determined by the attending provider) by having a mechanism for waiving the otherwise applicable copayment for the preventive services provided in a hospital.” This example shows how clinically-driven benefit design changes can be used to drive people to higher-value care without any negative impact on quality.

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 services?

Response: There is a wide scope of data available to help guide value-based decisions on treatment. Academic literature is a primary source of relevant information, which

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1 Letter from Doug McKeever, Interim Assistant Executive Officer, Health Benefits Branch of CalPERS to James Mahew, October 28, 2010. (This letter is attached to these comments with the permission of CalPERS).
may rely on narrow studies of single employer groups or a larger meta-analysis of Medicare claims data. Plans also continually assess their own data and Blue Shield of California has an internal analytics team that analyzes our own claims information. The availability and quality of this data should increase even more as comparative effectiveness research funded by PPACA begins to show results.

In addition, Blue Shield of California has engaged in cooperative ventures such as our collaboration with the non-profit Pacific Business Group on Health to drive better quality reporting measures for providers. The California Cooperative Healthcare Reporting Initiative (CCHRI), a collaborative of health care purchasers, consumers, health plans and physicians, worked together to measure the performance of 13,000 high-volume physicians on evidence-based healthcare quality standards. Additionally, the California Physician Performance Initiative (CPPI), a multi-stakeholder initiative run by physician organizations, health plans, purchasers, consumers and health data experts measures and reports on the performance of California's physicians. Started in 2006, CPPI aggregates claims data covering more than 5 million patients and 63,000 physicians to generate a reliable set of quality metrics. These types of collaborations provide reliable and transparent data that allow consumers to make better choices about their providers.

For example, academic evidence and internal claims data showed that there is a wide discrepancy in outcomes from bariatric surgery. Blue Shield convened an external panel of qualified physicians who agreed on the most appropriate quality measures and care processes. Physicians who met the quality measures and agreed to the care processes were then selected to be part of the plan’s provider network. This could be considered a VBID network because the determination of which providers would be in-network was based on cost and quality with the goal of improving the delivery of care.

5. How often do plans and issuers re-evaluate data and plan design features?

- How is the impact of VBID on patient utilization monitored?
- How is the impact of VBID on patient out-of-pocket costs monitored?
- How is the impact of VBID on health plan costs monitored?
- What factors are considered in evaluating effectiveness (for example, cost, quality or utilization)?

Response: VBID plans are still in their infancy and therefore they are constantly being adjusted based on new research data or internal claims data. VBID programs should be measured in relation to increased adherence to the desired clinical intervention, with an anticipated cost reduction being an associated longer-term benefit. The first measure of any VBID program is its impact on uptake and utilization of the targeted intervention. The second area of measurement is the longer-term cost trend. Since it may take three or more years for patients to show the benefits of increased utilization of preventive drugs or services, VBID programs must be given time to develop.
6. Are there particular instances in which a plan or issuer has decided not to adopt or continue a particular VBID method.

- If so, what factors did they consider in reaching that decision?

**Response:** We have heard that state regulators have suggested that VBID benefits which lower the cost of drugs for certain targeted chronic conditions (i.e. beta blockers for heart disease or insulin for diabetics) may raise issues under federal Mental Health Parity legislation. State regulators have suggested that in order to comply with parity requirements, any reduction in co-pays for these targeted interventions would have to be matched by equal reductions in co-payments for all drugs treating mental health conditions. We believe this misreads the Mental Health Parity law, specifically provisions regarding non-quantitative treatment limits. However, to ensure that plans are able to implement VBID programs without this significant regulator obstacle, it would be helpful for HHS to clarify that properly-constructed VBID programs do not implicate Mental Health Parity concerns.

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

**Response:** See answers #3, and #4 above.

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

**Response:** The real promise in VBID programs is to be able to specifically tailor benefits based on population characteristics. High-risk populations need effective, coordinated care and incentives to use medications to treat chronic disease more than low-risk populations. As a matter of health policy, there is no doubt that bending the cost-curve will require more and better coordination of care and targeted benefit designs (with appropriate safeguards) for high-risk populations. This can be done by identifying high-risk populations through wellness screenings and then providing incentives for high-risk populations to seek clinically appropriate care from the highest quality providers.

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

**Response:** The preventive services regulations already encourage the use of VBID programs for preventive care based on population characteristics. For example, the USPSTF recommendation for Type 2 Diabetes recommends screening for individuals with elevated blood pressure—i.e., those who are at a higher risk of diabetes. Therefore
the USPSTF recommendation is that diabetes screenings be provided at no cost-sharing only to high-risk populations, not to low-risk populations.

While the preventive services recommendations clearly distinguish between high-risk and low-risk populations, it is more difficult for plans to segregate treatments for these populations because ICD codes do not make distinctions between preventive and non-preventive treatments. Additionally, plans are still adopting the technology that will allow the necessary communication between providers and payers to allow the sharing of clinical and benefit design data on a real-time basis. It would be very difficult to estimate the cost of this transition, but it is expected to take place with the movement to electronic medical records as facilitated by the American Recovery and Reinvestment Act.

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 of care?

   - 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?

Response: VBID designs need to be robust enough to cover the broad majority of members in order for the benefit design to be effective. For example, a VBID program targeting diabetes would be ineffective if it covered only a single drug. Therefore the incentive in VBID programs is to make sure they are over-inclusive in providing incentives to utilize care rather than under-inclusive.

We provide coverage for the medically appropriate treatment in the medically appropriate setting, even if more expensive. The member cost-share may be higher for the non VBID treatment, but it will never be high enough to act as a barrier to treatment. While it may be appropriate to provide safety valves for high-risk individuals, it is important to remember that a robust legal and regulatory infrastructure exists to ensure that members have access to appropriate care. For example, California has extensive legal and regulatory requirements to ensure network adequacy, to require timely access to providers, and to prevent “illusory benefits.” All of these requirements protect patients to ensure they receive medically appropriate care. It would be inappropriate to impose significant new regulations on top of these when there is little if any evidence to suggest that VBID programs impose any substantive barriers to care.

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

Response: As mentioned above, a well-designed VBID strategy will always focus on ensuring that patients are receiving high-value care in the appropriate setting.
12. How are consumers informed about VBID features in their health coverage?

**Response:** Health plans will notify individuals of benefits in their EOC documents and may inform individuals of VBID benefits as part of their disease management programs—which may include newsletters and/or phone calls. Employers are often a major conduit of information on VBID programs because VBID programs are frequently linked to participation in wellness programs run by the employer. As more on-line tools become available, VBID designs will become much more interactive and integrated.

13. How are prescribing physicians/other network providers informed of VBID features and/or encourage to steer patients to value based services and settings?

**Response:** Physicians are informed through targeted outreach, newsletters and other communications about VBID programs. One area of real promise is the ability to integrate health information technology with VBID plan designs so that providers have real-time information on the benefits offered by a specific plan design.

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?

**Response:** As stated above, sufficient consumer protections exist in current state and federal regulations, including network adequacy requirements and timely access to care regulations. Furthermore, plans are required to provide access to preventive care at no cost-sharing in compliance with PPACA. Failing to meet these requirements could result in significant penalties under the Public Health Service Act. These regulations are more than sufficient to ensure that plans are meeting the requirements of Section 2713.

B. Comments Regarding Economic Analysis

A number of federal laws (e.g., the Regulatory Flexibility Act) require agencies to provide an analysis of the impact of regulations on small businesses or where there is an annual effect on the economy of $100 million or more.

1. What costs and benefits are associated with expanded use of VBID methods?

   - How do costs and benefits vary among different types of preventive screenings, lifestyle interventions, medications, immunizations, and diagnostic tests?

2. What policies procedures, practices and disclosures of group health plans and health insurance issuers would be impacted by expanded use of VBID methods?
- What direct or indirect costs and benefits would result?
- Which stakeholders will be impacted by such benefits and costs?

3. What impact would expanded use of VBID methods have on small employers or small plans?

- Are there unique costs or benefits for small plans?
- What special considerations, if any, should the Departments take into account for small employers or small plans?

**Response:** This question is difficult to assess without additional information on the regulations under consideration. Blue Shield does not have comments on the economic analysis besides emphasizing that VBID programs offer a significant and promising opportunity to bend the cost curve in health care. Numerous studies have already shown that VBID programs can improve health outcomes and lead to lower costs. As these programs become more refined and sophisticated, they may lead to significant gains in worker productivity and lower cost trends for health insurance. Any regulation of VBID programs must therefore consider the positive impact of expanding innovation in this area, as well as the corresponding negative impact of impeding the development of programs that may prove central to bending the long-term cost curve in health care.

Blue Shield of California remains committed to making health reform a success, and we look forward to working cooperatively on this and other issues to expand affordable access to health care.

Sincerely,

[Signature]

Andy Chasin
Associate General Counsel for Health Reform
October 28, 2010

James Mayhew
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
7501 Wisconsin Avenue, West Tower
Bethesda, MD 20814

Dear Mr. Mayhew:

Following up on our recent conversation, we are writing to request guidance on whether it is permissible to adopt a "value-based plan design" that includes no cost-sharing for colorectal cancer preventive services when performed in an ambulatory surgery center (ASC); and a required cost-sharing when the same preventive service is offered in a more costly (in-network) outpatient hospital setting. We have examined the "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" issued July 19, 2010 (OCIIO–9992–IFC) and find no clear answer to this question.

Background

In implementing plan changes effective January 1, 2011, we have noticed a problem in the Preventive Services Interim Final Rules (IFR) as they relate to value-based insurance designs. The IFR notes that "The Affordable Care Act gives authority to the Departments [of Health and Human Services, Labor, and the Treasury] to develop guidelines for group health plans and health insurance issuers offering group or individual health insurance coverage to utilize value-based insurance designs as part of their offering of preventive health services." (See Federal Register, Vol. 75, No. 137, p. 41729.) Consistent with this mandate, the IFR, at 45 CFR 147.130(a)(4), provides that nothing precludes "a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for any [preventive care] item or service...."

In June 2010, the California Public Employees' Retirement System (CalPERS) negotiated a value-based design for the Blue Shield of California HMO, regulated by the California Department of Managed Health Care (DMHC), beginning January 1, 2011. This value-based design was to include no cost-sharing ($0 co-pay) for colorectal cancer
preventive services when performed in an in-network ASC. In contrast, the same preventive service offered in an in-network outpatient hospital setting would require cost sharing (i.e., a $250 co-pay).

We believe this method of value-based design is consistent with the intent of the IFR to "promote access to and use of higher value providers, treatments, and services" as well as fostering better quality and efficiency by encouraging individuals to use lower cost (although not necessarily lower quality) treatment settings. CalPERS made this benefit modification for its 2011 plan year (prior to the release of the IFR) after its February 2010 Population Health Study revealed that colonoscopies performed in outpatient hospital settings were 2.5 to 3 times more expensive than the same procedure performed in an ASC without equating to superior care or higher quality.¹ Dr. R. Adams Dudley, University of California, San Francisco professor of medicine and health policy recently supported those findings in *Kaiser Health News* when he noted, "Some hospitals are able to charge higher prices than the market normally would bear, even without providing higher quality. That means they're getting those higher prices without really offering more to patients or the rest of society."²

When the preventive services IFR was issued, CalPERS health providers questioned whether a co-pay could be charged for preventive services provided at an in-network (albeit higher cost) outpatient hospital setting. CalPERS now seeks clarification as to whether it can implement the terms of its value-based plan design, including cost sharing for all in-network outpatient hospital colorectal cancer preventive screenings.

It is worthwhile noting that according to the report "Ambulatory Surgery in the United States, 2006" from the National Center for Health Statistics, the rate of procedures performed in ASCs is increasing rapidly and is approaching the rate of procedures performed in outpatient hospital settings.³ CalPERS Blue Shield of California HMO members receive approximately 12,000 colorectal cancer screenings per year. We have no evidence that there are any issues related to access for these services and on the contrary note that the DMHC heavily regulates California HMOs to ensure access.⁴ Blue Shield of California has over 450 contracting ASCs in its network. There are only 4 rural areas in the HMO service area throughout the state in which an enrollee would have to travel farther to receive services from an ACS than they would have to drive to a hospital.

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¹ Public findings of the study can be found at [http://www.calpers.ca.gov/index.jsp?bc=/about/benefits-overview/health/be-well-informed/related-articles/population-health-study.xml](http://www.calpers.ca.gov/index.jsp?bc=/about/benefits-overview/health/be-well-informed/related-articles/population-health-study.xml); the colonoscopy findings are in an internal report.


for the same service. In those instances an ASC is available in the next community to which an enrollee would commonly travel for tertiary care services.

Beyond the fact that the proposed ASC incentive policy would not undermine access to needed preventive services, there would be no diminution of quality or safety. For example, a 2003 study "Perforation During Colonoscopy in Endoscopic Ambulatory Surgical Centers" found that of 116,000 colonoscopies performed in one network of endoscopic ASCs, only 37 (0.03%) resulted in perforation.\(^5\) This compares favorably with the perforation rate of screening colonoscopies of 1 in 1,000 (0.1%) cited in "Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008."\(^6\) Similarly, a 2009 study "How Well Does Diagnosis-Based Risk-Adjustment Work For Comparing Ambulatory Clinical Outcomes?" showed no statistically significant difference in death rates after colonoscopies performed in ASCs versus colonoscopies performed in hospital outpatient settings in Florida.\(^7\)

Professional associations support the performance of colonoscopies in ASCs. The 2008 "Guidelines for Office Endoscopic Services" of the Society of American Gastrointestinal and Endoscopic Surgeons states that endoscopies can be performed safely in "facilities... certified as an Ambulatory Surgery Center."\(^8\) As noted in a 2009 letter from the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy, "The ASC is an important part of current GI practice, providing a safe, patient-friendly and cost-effective environment for the provision of medical services, such as colorectal cancer screening, for patients of all ages."\(^9\)

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Conclusion

At this time, we are requesting your guidance on whether we can proceed with the original value-based plan design approach. We firmly believe that this type of design innovation is necessary and that the intent of the law was to ensure that members have the greatest access to preventive services possible while allowing a reasonable degree of cost control without unreasonable bureaucracy. We believe that if the U.S. Preventive Services Task Force were to rate expensive services that have widely varying costs based on setting, the current IFR would prohibit health plans from imposing cost-sharing for the more expensive settings, thus causing an inefficient use of health care resources.

CalPERS and our health plan partners have more than 10 years of experience using innovative value-based plan designs for all services, including preventive services. On behalf of our 1.3 million members, and as the largest non-federal public purchaser of health care, we hope to serve as a best practices model.

We face impending deadlines to implement plan changes beginning January 1, 2011. We respectfully request approval to the extent possible on the preceding question no later than November 19, 2010, to provide sufficient time to inform members and our plan partners.

We are committed to being a collaborative partner in order to ensure the smooth and successful implementation of the new health care reform law. If you have any questions or wish to discuss these issues further, please contact Dr. Kathy Donneson, Chief, Office of Health Plan Administration, at (916) 795-0394. Thank you for your time and consideration.

Sincerely,

[Signature]

DOUG P. McKEEVER
Interim Assistant Executive Officer
Health Benefits Branch

cc: Ann Boynton
    Kathy Donneson