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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 (VBID)

Submitted via: www.regulations.gov

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

The Blue Cross and Blue Shield Association ("BCBSA") – representing the 39 independent Blue Cross and Blue Shield Plans ("Plans") that collectively provide health coverage to nearly 98 million members, one in three Americans – appreciates the opportunity to submit comments on the "Request for Information Regarding Value-Based Insurance Design in Connection With Preventive Care Benefits" as issued in the *Federal Register* on December 28, 2010 (75 Fed. Reg. 81544).

BCBSA supports efforts to modernize benefit design to promote prevention, wellness, and management of chronic conditions. As discussed in our responses below to the questions in the Request for Information (RFI), Plans have used value-based insurance design (VBID) as part of multi-faceted efforts to foster better quality and efficiency. And in the past, BCBSA has recommended that Medicare take steps to identify and test relevant value-based insurance designs.

We have two overarching recommendations that are included throughout our comments:

- First, because VBID is still an emerging area with considerable promise, it is critical that health plans have the flexibility to experiment and to innovate. Any future regulations or

guidance should not inadvertently lock health plans into one approach, or call for unrealistically swift results because the returns to VBID may take two to three years to accumulate.

- Second, plan design tools that incentivize consumer behavior, such as cost-sharing mechanisms and network design features, are central to good benefit design in general. Every VBID incorporates cost-sharing or network features, but every plan design that incorporates cost-sharing and network features is not VBID.

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RESPONSES TO THE REQUEST FOR INFORMATION REGARDING VALUE-BASED INSURANCE DESIGN (VBID) IN CONNECTION WITH PREVENTIVE CARE BENEFITS

1. *What specific plan design tools do plans and issuers currently use to incentivize patient behavior?*

   The basic premise of VBID is to align patients' financial incentives with the value of health services. This is also a basic premise of good health plan benefit design in general, hence the use of tools such as network design features and variations in cost-sharing to help members achieve improved health outcomes at an affordable cost.

   - If a plan waives cost sharing for certain services provided in-network while imposing cost-sharing for services provided out-of-network – as the Preventive Services Rule allows for recommended preventive services – then the plan is fostering better quality and efficiency in general.

   - Similarly, if a plan waives cost sharing for certain services provided at relatively low cost in one kind of in-network setting while imposing cost-sharing for services provided in other, higher-cost in-network settings, where quality is equal in either setting – as the Preventive Services Rule provides, for example, in allowing plans to charge for colorectal services provided in a hospital outpatient department instead of an ambulatory surgery center – then the plan again is fostering better quality and efficiency.

   Both examples of targeted cost-sharing and specific network design features are consistent with the basic premise of VBID, but they are not examples of VBID per se.

   Therefore, we recommend that the Departments distinguish between plan design tools that are necessary, in general, for affordable and effective benefit packages – even if consistent with VBID – and design tools that are intended expressly to implement a VBID feature by reducing barriers to high-value treatments (through lower costs or other financial inducements to patients).

   We provide examples of specific VBID design tools in the response to the next question.

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)?*

Blue Cross and Blue Shield Plans ("Plans") have applied VBID to broad populations – such as by reducing or eliminating cost-sharing for generic drugs – and to targeted populations.

Some Plans have found that VBID is most effective when it targets populations at greatest risk for high costs. For example, one Plan achieved high success by adding VBID tools as an adjunct to an existing disease management/care coordination program for one employer's members who had asthma or diabetes.

- Asthmatic/diabetic members were eligible for free generic formulary maintenance medications and $5 brand formulary maintenance medications (the regular copayment was between $20 and $30) used for asthma/diabetes and for any co-morbid chronic conditions.

- The target population was identified by medical claims in the pre-intervention period; participation was voluntary and was requested by an invitation letter that described the intervention and included consent and enrollment forms.

- To be eligible, members had to agree to: (1) See their physician as recommended; (2) Report screening results and other related clinical metrics to their disease management program care coordinators; (3) Talk with their disease management program care coordinators when they were called for a follow-up. (The Plan customized the frequency of telephonic outreach based upon the member's condition severity and the clinical judgment of the care coordinators.); and (4) Fill their asthma and diabetic medications as directed by their treating physician.

This program was highly effective as measured by the following metrics:

- The group that received VBID incentives had fewer inpatient admissions, outpatient services, and emergency room visits than the non-incentivized group.

- Spending per member per month in the VBID group compared with the non-incentivized group was 5% lower for asthmatics and 25% lower for diabetics.

- Medication compliance and condition-specific screening/services were higher for the asthmatic/diabetic population as a whole. For example, flu/pneumococcal vaccine compliance increased from 39% to 70%, an 80% increase; and diabetic retinal examination increased from 23% to 85%, a 269% increase.

It bears noting that the program components considered essential to the success of this VBID model included not only targeting the percentage of the population at greatest risk for high costs, **but also linking financial incentives to active participation in the disease management program**.

Another Plan implemented a pilot VBID program targeted at members with diabetes to increase active participation in a disease management program built around health coaching: nurses and dieticians worked with members telephonically to address their specific health education needs. The goal of this disease management program is to promote members' ability to better self manage their conditions, maintain compliance with tests, exams, and medications, and ultimately reduce serious complications such as heart disease and kidney failure.

- Using medical and pharmacy claims data, the Plan identified eligible members within three employer groups.

- Members were asked to (1) complete, sign, and send a pledge to adopting healthy behaviors and striving to reach self management goals; and (2) contact the disease management program to arrange an initial assessment.

- Upon completion of these two steps, the Plan reduced the copayment to $2 per month for all oral hypoglycemic agents and insulin products regardless of formulary tier status.

The Plan calculated the medication possession ratio (MPR) for the 6 months prior to the program start and the 6 months of the pilot phase, broken out by participating and non-participating groups. Compliance was defined as an MPR greater than .80 (80%). For those members who did enroll and were non-adherent, MPR increased 1% point in the pilot phase; those who were adherent increased their medication possession ratio by 4%.

In these two examples, Plans used claims data to identify the target population. Another approach to identifying populations-at-risk is through Personal Health Assessments or Health Risk Appraisals. Plans have used VBID tools to encourage individuals to complete these screenings. For example, under one "Screening Incentive Program" that a Plan makes available to employer groups:

- Employees complete an on-line, annual health assessment.

- Employees receive a "scorecard" of recommended screenings, which the Plan tracks through claims data. Employees receive a second scorecard with reminders, and then a final report of participation.

- Employees who participate receive incentives designed by the employer: for example, the employer may contribute a higher portion of the employee's premium, or offer a fitness-related gift such as a bicycle.

Another Plan offers an online health tool program:

- As an eligible member participates on the online health tool, points accrue for specific actions taken by the member.

- At the end of the calendar year, members may redeem their points with a maximum of $250 at an online redemption center.

These Plan programs illustrate the potential benefits of using VBID to promote desirable behaviors, such as participating in a disease management program or completing a health assessment. **Therefore, in future regulations or guidance that the Departments may issue, we recommend that plans have the flexibility to lower costs to patients who participate in such high-value programs or otherwise engage in desired behaviors.**

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

Quality and safety are primary drivers in steering patients to a particular setting or provider: if a particular setting or provider (or tier of providers) can provide equal or better quality at lower cost, Plans would view that as constituting acceptable value.

The core sources of data are medical and pharmacy claims. But Plans also seek insights into their members' health from laboratory claims data, satisfaction surveys (such as the Consumer Assessment of Healthcare Providers and Systems), voluntary personal health assessments, utilization management determinations, and information collected by disease management or care coordination programs.

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?*

   Plans mine their claims data – which may, depending on the population, be augmented by some or all of the data sources mentioned above – to identify opportunities for care intervention, benefit modification, care program expansion, and consumer education.

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

   Our response to question 2 gives examples of how Plans have evaluated the effectiveness of VBID design features.

   In general, Plans reevaluate data and plan design features periodically throughout the year. Frequency of the data analysis depends upon the goal. For example, a Plan may monitor strategy-specific goals on a monthly basis to ensure that the trends are shifting in the desired or anticipated direction. A Plan may also monitor new products more closely after release to the market to ensure that it is attracting the volume of business and the demographic that was targeted. New products may be monitored weekly during open enrollment.

   Data evaluation around standard plan design may take place quarterly. This data evaluation could include reports that provide information on enrollment trends, shifts in buying patterns for cost sharing/plan design, competitive intelligence, and profitability data. Some Plans share findings and strategies with a cross-functional team of representatives to seek feedback for their specific area of expertise and pertinent feedback is then incorporated into the plan design strategy.

   For VBID features in particular, where experience is still in the early stages, it is critical that Plans retain the flexibility to experiment and innovate and not be locked into one approach – especially since the returns on VBID often accumulate only after two to three years. Health plans need the flexibility to engage in everything from simple trial-error-refinement to rigorously designed pilots that give health plans time to evaluate lessons learned, and then redesign accordingly, with an adequate, multi-year time horizon.

6. *Are there particular instances in which a plan or issuer has decided not to adopt or continue a particular VBID method?*

If a particular VBID method does not achieve improved health outcomes or, because of the law of unintended consequences, actually raises costs without improving health outcomes, then a plan may decide to revisit the method. For example, one Plan 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 that did not correspondingly yield clinical benefits.

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

   Plans will apply the criteria generally used for making plan design decisions: will it ensure consumers get the right care at the right time and in the right setting; is there a sound evidence base weighing considerations of cost-effectiveness, quality and appropriateness; and will it balance the need to provide reasonable, appropriate, high quality coverage with the need to assure affordability and access for consumers?

   We strongly urge that any criteria that the Departments may follow or adopt should allow for plan innovation and flexibility to meet evolving market and consumer needs.

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)?*

   Plans already vary cost-sharing requirements for the same service based on population characteristics, as when members eligible for a disease management program pay lower copayments for drugs than members who are not eligible. As health 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 VBID in an increasingly clinically-nuanced fashion.

   As an example of more refined predictive modeling, one Plan uses data from a wide variety of sources (including incurred claims, adjudicated claims, pharmacy claims, worksite screenings, health/risk assessments, UM determinations) to identify and stratify patients with greatest needs who could benefit most from an intervention. The Plan further identifies opportunities by looking for “gaps” in care like missing medications, ER visits, and hospital admissions. Each member is assigned an index score that identifies members with the greatest opportunity for change (e.g., someone with severe diabetes who is already seeing their physician regularly, taking all medications, etc., is a low opportunity). Plans using such refined techniques might want to tailor cost-sharing requirements to very specific population characteristics.

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?*

   A key data requirement would be information on gaps in care based on practice guidelines.

   Administrative costs will depend upon the program design. For example, a VBID program may require extensive targeted communications or information system modifications, all of which would raise administrative costs. In general, the administrative costs associated with

implementing VBID may be relatively high because of the analytical reporting costs. Requirements for additional infrastructure, for sharing information (claims and clinical data), and for legal and regulatory compliance add complexity.

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? 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 have mechanisms to identify and help the minority of patients for whom a higher cost service may be medically appropriate. Using predictive modeling to project the likelihood of members incurring future costs or receiving certain services, and mining data to identify gaps in effective care, a Plan may determine that certain members with a chronic or a prolonged illness would benefit from complex case management or a highly specialized disease management program. Then Plans generally reach out to these members to make them aware of their unique options and put them in touch with the specialized case/disease management programs.

    If the Departments wish to address "safety valves" in future regulation, we recommend giving health plans the flexibility to guide (through requirements or incentives) the minority of patients for whom a higher-cost service may be appropriate to such alternative mechanisms as a complex case management program.

    In addition, health plans generally have exceptions processes where medical or pharmaceutical managers – often with the direct involvement of a medical director – will review unique or special circumstances that may require a patient to receive a "higher-cost" item or service. It is common, for example, for Plans to have a member-initiated exception process for non-formulary drugs, where a member may ask for an exception request prior to purchasing a non-formulary drug: e.g., if there is only one alternative to the non-formulary medication and treatment with a formulary medication is contraindicated, ineffective, or not tolerated, then an exception may be made to prior authorize the non-formulary medication.

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

    Ensuring adequate access to the right care at the right time is critical to good benefit design in general, not unique to a VBID strategy. In addition, state laws set network adequacy and other network requirements where plans must demonstrate that they have adequate access to all specialties of care.

12. *How are consumers informed about VBID features in their health coverage?*

    Plans use a wide variety of methods to inform consumers about features of their health coverage: benefit plan information provided upon enrollment; special mailings; on-line tools and services through member-oriented websites; emails to individuals and to employer groups – some Plans pre-package emails for employers to share with employees; and

member contact centers. Some Plans also operate walk-in "retail centers" that offer special educational sessions.

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

    Plans use a wide variety of methods to inform providers about benefit and medical policies: monthly newsletters that raise awareness among physicians and hospitals and encourage them to engage patients; fax blast bulletins or mailed bulletins; e-alert communications or bulletins; outreach visits by a Plan's "Provider Relations" unit; seminars and workshops; administrative manuals/tool kits; and webinars. Plans also make information available via web site provider portals.

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?*

    Current state and federal laws ensure that consumers receive needed protection. The Affordable Care Act adds to existing protections with specific provisions related to network adequacy.

    However, there is one exception specific to the provisions of PHS Act section 2713: consistency around what is considered required preventive care services. For example, section 2713 provides that plans cover as benefits recommendations of the United States Preventive Services Task Force (Task Force) that have in effect a rating of 'A' or 'B'. Because these recommendations, developed by panels of clinicians for use by other clinicians, were never intended to be used for coverage purposes, they lack the precision of standards developed expressly for the purpose of providing coverage of health care services. And having been developed by different panels of experts over many years, the language contained in the recommendations is not always consistent.

    As a result, many of the Task Force recommendations contain ambiguities that will lead to varying interpretations. Moreover, because the current sets of ICD-9-CM and CPT codes have limitations that make it impossible to recognize the covered preventive services in every claim situation, different organizations will develop different coding algorithms to identify covered services within claims for adjudication, leading to variations in coverage determinations.

    Therefore, BCBSA again respectfully requests (as we did in our previous comment letter) that the Departments issue sub-regulatory guidance defining each recommendation more precisely by providing guidance on options for coding to make benefit determinations. If the Departments are unable to provide a clear understanding on how to code a benefit, then coverage of that benefit should be pended until the appropriate codes become available. Options for coding would include indicating which recommendations should be provided during comprehensive preventive medical visits.

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We appreciate the opportunity to respond to the RFI and thank you for considering our comments and recommendations. We look forward to continuing to work with the Departments on implementation issues related to VBID. If you have any questions, please contact Joel Slackman at Joel.Slackman@bcbsa.com or 202.626.8614.

Sincerely,

Justine Handelman
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