

February 28, 2011

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210
Attention: VBID

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

Dear Sir or Madam:

HR Policy Association (“HR Policy”) and the Pacific Business Group on Health (PBGH) are submitting comments in response to the request for information on how group health plans can employ VBID in the coverage of recommended preventive services under provisions of the Patient Protection and Affordable Care Act (PPACA; Public Law 111–148), amended by the Health Care and Education Reconciliation Act (Public Law 111–152). The RFI was issued by the Departments of Labor, Health and Human Services, and Treasury (the “Agencies”) and printed in the Federal Register on December 28, 2011 at 75 Fed. Reg. 81544. According to the RFI, these comments will be shared with the Departments of Health and Human Services and Treasury.

HR Policy represents the chief human resource officers of over 300 of the largest employers doing business in the United States. Representing every major industrial sector, HR Policy's members employ more than 18 million people worldwide and collectively spend more than \$75 billion annually providing health insurance to millions of American employees, their dependents and retirees.

PBGH is a business coalition of 50 purchasers that seeks to improve the quality and availability of health care while moderating cost. Since 1989, PBGH has played a leading role both nationally and statewide in health care measurement, trend moderation, and provider accountability through public reporting.

Section 2713 of the Public Health Services Act as added by Section 1001 of PPACA requires a group health plan and a health insurance issuer to provide coverage benefits for and prohibit the imposition of cost-sharing requirements with respect to certain preventive coverage services. The Agencies published interim final regulations implementing these provisions on July 19, 2010 at 75 FR 41726.

Many of our member companies offer comprehensive health care benefits for their employees and their families, including preventive services. Some of these organizations have a long history of value-based purchasing of health care and were early innovators in advancing value-based benefit design.^{1 2} Examples include:

¹ Robert Galvin, MD, and Arnold Milstein, MD MPH, Large Employers' New Strategies in Health Care, N Engl J Med 2002; 347:939-942 (Accessed at <http://www.nejm.org/doi/full/10.1056/NEJMs012850>)

² Niteesh K. Choudhry, MD, Meredith B. Rosenthal, PhD, and Arnold Milstein, MD MPH, Assessing The Evidence For Value-Based Insurance Design, Health Affairs, 29, no.11 (2010):1988-1994 (Accessed at <http://content.healthaffairs.org/content/29/11/1988.full.html>)

- Pitney Bowes used predictive modeling and claims analytics to design a strategy to integrate health management with specific coinsurance reductions for maintenance medications targeted at specific chronic conditions³;
- General Electric implemented UnitedHealthcare's Diabetes Health Plan which reduces or waives copays for specific services when a member adheres to recommended diagnostic screening guidelines and biometric values (lab results, body mass index, etc.);
- IBM, UPS, and Verizon, among others, have implemented patient-centered medical home pilots that feature an enhanced primary-care model with comprehensive and timely care with appropriate reimbursement, emphasizing the central role of teamwork and engagement by those receiving care;
- Marriott International, Inc. provides free annual check-ups, pre-natal care and immunizations to its employees and their dependents⁴;
- The Boeing Company has piloted an Intensive Outpatient Care Program that promotes care coordination, practice redesign and provider payment reform to support members with complex care needs;⁵
- CalPERS, Union Bank, University of California and Wells Fargo, among others, offer high performance provider network options;
- McKesson, Cisco Systems, among others, offer varied incentives for completing health risk appraisals, engaging in health coaching and participating in condition management programs as appropriate.

The following responses to the RFI reflects benefit designs and incentives that have been used by various purchasers in a variety of health plan options, including insured and self-insured PPO, HMO and consumer-directed health plans.

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

Purchasers design health benefit programs with the objective of improving the health of their populations while optimizing the value of those health care dollars and moderating costs. The VBID tools our members use to impact consumer behavior encompass a broad range of coverage rules, cost-sharing and use of incentives, including:

- Differentiating and recognizing higher-performing providers and networks to encourage consumers to select them;
- Prescription drug options that may include reduced copayments or coinsurance for selected medications to improve adherence with the goal of reducing morbidity and complications for select health conditions;
- Decision support tools for treatment option selection that provide patients with information about risks, benefits and potential outcomes of selected services, while recognizing an individual's preferences;
- Encouraging adherence to evidence-based preventive medical and diagnostic services, and
- Wellness and condition management programs that include health promotion, reducing high risk behaviors, self-care, health coaching, disease management and case management.

³ John J. Mahoney, MD, MPH, Value-Based Benefit Design: Using a Predictive Modeling Approach to Improve Compliance, J Manag Care Pharm. 2008;14(6)(suppl S-b):S3-S8 (Accessed at http://www.amcp.org/data/jmcp/JMCPSuppB_S3-S8.pdf)

⁴ Martin Sipkoff, Value-Based Insurance Design: Spend a Little More On Selected Patients For Payoff Down the Line, Managed Care August 2009 (Accessed at <http://www.managedcaremag.com/archives/0908/0908.vbid.html>)

⁵ Arnold Milstein, MD MPH, and Pranav Kothari, MD, Are Higher-Value Care Models Replicable?, Health Affairs Blog, October 20, 2009, (Accessed at <http://healthaffairs.org/blog/2009/10/20/are-higher-value-care-models-replicable/>)

Within each of these areas, purchasers use various financial levers to engage consumers, which may include:

- Cash awards for participation, completing certain activities, or achieving a goal (or improving risk status or attaining biometric value);
- Premium reduction through a contribution adjustment, usually applied prospectively and distributed across an organization's payroll cycle;
- Premium contribution holiday for a defined period;
- FSA or HSA contributions;
- Access to enhanced benefits or programs (lower copays, deductibles), and
- Other non-cash rewards (gift cards, prizes, lotteries, etc.)

How is effective defined?

Employers evaluate effectiveness in a number of ways, and the definition changes periodically as information about the most effective benefit designs evolves. Assessing the return on investment is one approach, but must be taken in the context of total health care and workplace costs, including impacts on presenteeism, absenteeism and short-term and long-term disability.

Examples include:

- Improved adherence to evidence-based medicine, such as recommended diagnostic screenings for preventive care or managing chronic conditions;
- Increased use of high performing doctors and hospitals;
- Increased use of primary care or urgent care facilities relative to lower emergency department use, with associated reductions in ambulatory care-sensitive admissions or avoidable hospital readmissions;
- Improved adherence to maintenance medications and/or drug possession rates ;
- Reduced use of rescue medications or other higher cost interventions for acute episodes that are avoided;
- Improved member engagement and/or participation in self-care and risk reduction programs;
- Reduced "gaps in care" or health risk factors, and
- Improved patient experience and clinical outcomes (which may be reported through patient surveys, biometric testing or diagnostic laboratory results).

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)?

The aforementioned plan design tools and related incentives impact a range of benefits for preventive care. For the general population, purchasers use VBID for preventive care to ensure patients receive high value, clinically appropriate treatment. For individuals with specific conditions, purchasers want to ensure they receive certain targeted services to maintain or improve those conditions. The services provided might be organized into primary prevention, secondary prevention, and specified preventive care services as recommended by the U.S. Preventive Services Task Force (USPSTF). VBID tools and incentives are also applicable across the continuum of services that extends to health coaching for risk reduction and behavior change, disease or condition management, and case management where appropriate.

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

Distinguishing high- and low-value services needs to be grounded in evidence-based medicine, standardized quality of care measures and cost-effectiveness. There is significant variation in provider practice and evidence-based guidelines, as has been well-documented in the clinical research literature – just 55% of adults receive recommended preventive care.⁶ We believe that the determination of high and low value services should be supported by comparative effectiveness research that addresses both quality and cost. Purchasers and plans have used such data to differentiate cost-sharing based on provider selection and site of service. While cost-sharing may be lowered in conjunction with selection of a high performing provider, member out-of-pocket expense may also be higher for a lower-value treatment setting or provider. Examples include reference pricing for preventive services such as colonoscopies but can also extend to other services such as orthopedic hip or knee joint replacement.

The time frame used for assessing value can vary significantly, from an annual premium rate renewal cycle to a multi-year, longer term perspective. For employers that have low turnover and high retention rates, a longer-term view provides a more comprehensive assessment of the value of benefit design incentives.

Claims and health risk appraisal data have been commonly used as sources of information for assessing results. Utilization indicators such as reduction in emergency department visits or avoidable hospital readmissions can be short-term indicators of “value,” but need to be considered in conjunction with measures of quality and clinical outcomes. While HEDIS has been a common standard for a number of preventive care measures, it is important to consider new sources of data that provide an enhanced view of functional outcomes and clinical results. For example, as the Meaningful Use criteria expand to include additional quality measures drawn from electronic health records, these data should be incorporated into value assessments.

Currently, data are generally not available from public sources. However, as the US Health & Human Services Department builds upon its Community Health Data Initiative, the regulations should consider ways in which to expand access to clinical information to support the development of more robust “value” metrics, recognizing HIPAA privacy and security regulations. A broader set of metrics could include benchmarks and performance thresholds for the following:

- Clinical outcomes,
- Functional status,
- Appropriateness,
- Patient experience,
- Care coordination and care transitions,
- Cost, and
- Resource use.

⁶ Elizabeth A. McGlynn, PhD, Steven M. Asch, MD, MPH, John Adams, PhD, et al. The Quality of Health Care Delivered to Adults in the United States, N Engl J Med 2003; 348:2635-2645 Accessed at <http://www.nejm.org/doi/pdf/10.1056/NEJMsa022615>

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?

Multiple data sources are currently in use and they constantly evolve. While health risk appraisal and medical, behavioral health, and prescription drug claims are most commonly available, some employers have invested in biometric testing to support consumer decisionmaking. Other sources of information include data from medical literature, consultants, public health information and analyses from health insurers, third party administrators, and data warehousing and medical informatics vendors.

It is important to note that a financial incentive alone may not be sufficient to steer patients towards high-value services or away from low-value delivery mechanisms. Data from behavioral economics research have also been useful in understanding effective ways in which to structure choice and frame communications.

- 5. How often do plans and issuers re-evaluate data and plan design features? What is the process for re-evaluation? Specifically:**
- a. How is the impact of VBID on patient utilization monitored?**
 - b. How is the impact of VBID on patient out-of-pocket costs monitored?**
 - c. How is the impact of VBID on health plan costs monitored?**
 - d. What factors are considered in evaluating effectiveness (for example, cost, quality, utilization)?**

As noted above at the end of Question 1 on measuring effectiveness, there are a variety of patient utilization indicators including but not limited to:

- Increased use of primary care or care coordination services;
- Increased use of high-value providers or preferred sites of service;
- Fewer emergency department visits or inpatient admissions that reflect reductions in avoidable complications;
- Patient engagement in health coaching or health management services, and
- Reductions in “gaps in care” such as completion of condition-specific diagnostic screenings or improved medication adherence/possession rates for chronic conditions.

The impact on patient out-of-pocket costs and health plan costs can be readily tracked through claims. It is important to note that some categories of expense such as drug costs may increase in conjunction with other reduced medical expense. If a design strategy involves lowering copayments/coinsurance to increase compliance, it is important to capture the costs of forgone copayments/coinsurance among the already compliant population compared to those who move from being non-compliant to compliant in assessing the overall value proposition of VBID. Employers work with health plans to identify control populations to support their evaluation of specific VBID changes.

There are many interconnected factors in assessing return on investment. While health plan costs are often assessed based on an annual premium rate renewal cycle, a multi-year, longer term perspective is important for certain conditions such as avoided cardiac complications in a well-managed diabetic population. It is often difficult to attribute health status improvement or risk reduction to any one factor such as a shift in cost-sharing or engagement in health coaching and behavior change. The effect of patient shifts to higher-performing providers may lend itself to valuation, but changes in provider cost profiles or contracting may also confound such an analysis. A longer-term view may also be required to

assess the impact on workplace productivity, using indicators such as presenteeism and absenteeism.

PBGH has collaborated with Milliman with support from Sanofi-Aventis to define metrics to help quantify the impact of various value-based benefit design interventions.

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?

As discussed above in the response to Question 4, defining high value care is a dynamic process, and what is considered appropriate care today may change as Purchasers work with their health plans, PBMs, and health management vendors to continually assess the impact of member engagement strategies, incentive designs and program performance. While a financial incentive may generate a short-term impact, employers are concerned with maintaining patient engagement over the long term and adjust strategies accordingly.

There are examples of employers discontinuing a particular VBID method. For example, a company that used to include all asthma drugs on its formulary without requiring a copay found it difficult determine whether the design was resulting in any improvement in consumer behavior. As a result, it discontinued the practice. In another instance, a company discontinued covering a drug without cost sharing after it became apparent that the medication did not work alone, but needed to be taken with a primary diabetic medication to be effective. The company amended its plan design to offer the drug without cost sharing only when it was offered with a primary diabetic medication.

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

Beyond using evidence-based clinical guidelines, population health analysis and risk assessment are important criteria to consider when designing a value-based benefit design strategy. Arguably, most populations would benefit from incentives to use treatment option decision support and select higher performing providers. However, in a given market, an employer may already have a high proportion of members using such providers. Similarly, in considering a potential copayment or coinsurance reduction for select drug classes, an employer may find that they already have a high adherence and drug possession rate, but that their "value" opportunity lies in improved generic substitution.

Designing a condition-specific intervention or adopting incentives for preventive care should be data-driven. Many large employers offer comprehensive preventive benefit programs such that cost-sharing may not be a significant barrier to adherence; additional factors such as primary care physician access and member education should be considered. The health needs of a population may vary depending on demographics and geographic utilization patterns. The degree of quality gaps relative to recommended clinical guidelines may reflect provider practice patterns and not be driven by cost-sharing considerations.

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)?

It is common to stratify a population to identify specific risks and interventions. Specific designs such as rewards for participation in a condition management program may result in availability of additional incentives for high-risk individuals.

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?

The complexity of the data requirements to support implementation of value-based benefit design is commensurate with the range of interventions and design features, the selectivity of the targeted population and associated “triggers” that qualify a member for receiving a particular benefit. For example, consideration of offering a high performance network option might rely on a relatively simple geographic analysis and the percentage of members attributed to providers outside of such a network.

To optimally support design selection, implementation, measurement and evaluation, there would need to be a comprehensive database of medical, behavioral health, and prescription drug claims, augmented by lab values or biometric data from worksite health fairs or electronic health records, and health risk appraisal information on self-reported risk factors. Analytic tools might include quality measurement (HEDIS, ambulatory care sensitive admissions), utilization review, adherence to evidence-based guidelines, risk stratification, and gaps-in-care identification. A claims-based system supports retrospective look-back but may be inadequate to support an incentive to use treatment option decision support, for example. If a desired intervention requires *prospective* information, integration with a health plan’s utilization review and authorization system is required. Additional information may include tracking of an employee or dependent’s affirmative enrollment in a program. Survey-based information may need to be integrated from an external vendor as well. Real time data integration to support health coaching activities is difficult to achieve, as is information exchange between a health plan and provider to reinforce goal-setting or behavior change priorities.

Effective tracking of behavior change over time requires robust health information exchange to capture self-reported information or integrate vendor-based information, and can be complicated by verification requirements (e.g., participation in a tobacco cessation program vs. successful program completion vs. maintenance of a tobacco-free status post intervention validated by nicotine testing). Similarly, rewards based on attainment of biometric targets require an administrative infrastructure, and potentially more challenging data collection processes if an employee’s dependents are separately qualified for incentives. If there are incremental incentives such as health risk appraisal completion, participation in health coaching and/or condition management programs, tracking completion and linkage to a differential benefits coverage program requires enrollment reporting, with defined qualification periods if applicable. Similarly, disqualification from a copayment or coinsurance waiver program may require tracking of participation or biometric values.

If an incentive involves a contribution strategy reduction or premium holiday, data must be integrated with an organization’s payroll system. Similarly, an FSA or HSA-based incentive requires integration with a banking institution. An incentive with a payroll tax impact also adds complexity.

Beyond defined member participation criteria, member engagement may require a consumer Web portal for information or rewards tracking and reporting that is different than the management reporting system needed by an employer to inform policy and budgeting

requirements. HIPAA considerations and information security may create barriers for engaging dependents, given corporate firewalls or requirements for secure exchange of protected health information, which limits use of corporate email systems.

Tracking up-to-date employee contact information is a difficult, but critical administrative requirement if the value-based benefit design program necessitates outbound calls or push-emails and text messages. Individual participant-level confidentiality issues arise for certain programmatic areas such as depression screening.

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?

Purchasers carefully design VBID plans to ensure all participants have access to medically appropriate care. This is built into existing plan designs used by large employers. For example, some employers use health coaches and advocates from the carrier or an independent vendor to provide navigational support and guide participants through the health plan and delivery system.

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

As stated above in our response to Question 1, large employer purchasers design health benefit programs with the objective of improving the health of their populations while optimizing the value of the health care dollars spent on benefits. Their perspective on value-based benefit design is broader than encouraging the use of preventive services; it encompasses coverage rules, cost-sharing and use of incentives that impact a consumer's decisions in any of several key domains:

- Provider selection and differentiating networks to recognize higher-performing providers;
- Prescription drug options that may include reduced copayments or coinsurance for selected medication to improve adherence with the goal of reducing morbidity and complications for select health conditions;
- Treatment option decision support that provides patients with information about risks, benefits and potential outcomes of selected services, while recognizing an individual's preferences;
- Adherence to evidence-based preventive medical and diagnostic services, and
- Health promotion and condition management programs that reflect the continuum of wellness, risk reduction, self-care, health coaching, disease management and case management.

Some employers offer a high performance network option alongside a health plan's broad network, using a contribution strategy differential to pass through the value of the high performance network to the employee. Others may offer a differential copayment or coinsurance to incent selection of a higher performing physician or hospital. In some cases, a health plan may require use of Centers of Excellence which have demonstrated better outcomes for specific services such as transplant surgery or bariatric surgery, and cover travel costs for plan participants to use these designated facilities.

An employer may link reduced cost-sharing for condition-specific services (e.g., reduced copayment or coinsurance for diabetes medications or blood sugar testing supplies) with other wellness initiatives (e.g., smoking cessation or weight loss) to increase the efficacy of both offerings. Approaches to increasing the impact of Health Risk Appraisals include introducing or increasing financial incentives for participation, explicitly linking the results of the appraisal with health coaching or other disease management programs, and offering incentives for achieving measurable risk reduction.⁷ Linking cost-sharing modifications to risk reduction increases individual accountability for changing behaviors that may exacerbate a chronic condition. As an added incentive to engage in a preventive care screening, a value-based benefit design enhancement could also be targeted at reducing barriers to effective follow-up therapies required to treat a newly identified condition.

Patients that engage in treatment option decision support often elect a more conservative, and less costly treatment than individuals who do not have access to such services.^{8,9} The combination of risk factor education and information about disease progression and functional outcomes, when weighted with a patient's preferences, contribute to a more informed decision. A value-based benefit design could discount patient out-of-pocket expenses after use of a decision aid, regardless of the subsequent choice of treatment.

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

Consumers enrolled in VBID plans typically receive communications in variety of formats including online, and in hard copy format regarding their benefits and various health promotion and condition management programs. Some employers also provide Spanish or other language translations of such material, which may be distributed through an annual open enrollment period or as part of regular employee and beneficiary communications. Other venues include employer-based Web portals, health fairs, podcasts, email or text messages. Specific examples may include:

- State and federal required Explanation of Coverage (EOC) and Standard Plan Document (SPD) information provided to prospective enrollees and on enrollment in coverage;
- Outreach to specific populations about both general and targeted programs through plan newsletters, websites, IVR or live phone calls to members, or e-mail; and
- Newsletters, employer websites, special workshops, programs or meetings, or posters.

Below is an example of an enrollment tool provided by PBGH to the University of California to support employee engagement in preventive and risk reduction services.

⁷ Haiden A. Huskamp and Meredith B. Rosenthal, Health Risk Appraisals: How Much Do They Influence Employees' Health Behavior?, *Health Affairs*, 28, no.5 (2009):1532-1540, (Accessed at <http://content.healthaffairs.org/content/28/5/1532.full.pdf+html>)

⁸ Annette M O'Connor, Alaa Rostom, Valerie Fiset, et al., Decision aids for patients facing health treatment or screening decisions: systematic review, *BMJ* 1999; 319 : 731, (Accessed at <http://www.bmj.com/content/319/7212/731.full.pdf>)

⁹ John E. Wennberg, MD, Annette M. O'Connor, E. Dale Collins, Extending The P4P Agenda, Part 1: How Medicare Can Improve Patient Decision Making And Reduce Unnecessary Care, *Health Affairs*, 26, no. 6 (2007): 1564-1574, (Accessed at <http://content.healthaffairs.org/content/26/6/1564.full.pdf+html>)

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✓ **Tips:** To compare the plans' features on topics that are important to you, click on "More". See more wellness information at [Wellness Resources for UC Medical Plans.](#)

Plan	Seeing a Doctor	Wellness Resources	How to Save Money
Kaiser Permanente CA HMO	PCP selection encouraged, but not required. Referral required for most specialists; can self-refer for ob/gyn and mental health.	Plan has nutrition & weight management program. More... Online personal health record includes email your doctor, get test results and appointment scheduling online More... Plan has stop smoking program. More... Plan has health assessment program. More...	You pay copays for doctor's office visits. Must select in-network providers. More...

Plan	Stop Smoking
Kaiser Permanente CA HMO	Free program includes help quitting through in-person and phone counseling; online, self-directed education program, with individualized smoking cessation plan. Group classes offered. Most classes provided at no charge to members. Over-the-counter aids (nicotine patch, gum). Helpline for referrals to community resources.
Health Net Blue & Gold HMO	StayWell free program includes an online assessment of your needs and ways to change behaviors. Get online education help for how to quit, handling quit day and withdrawal symptoms, nicotine replacement therapy and more. For high-risk members, get help by phone from a wellness coach and additional educational materials.
Health Net HMO	StayWell free program includes an online assessment of your needs and ways to change behaviors. Get online education help for how to quit, handling quit day and withdrawal symptoms, nicotine replacement therapy and more. For high-risk members, get help by phone from a wellness coach and additional educational materials.
Anthem Blue Cross PPO	StayWell free program includes an online assessment of your needs and ways to change behaviors. Get online education help for how to quit, handling quit day and withdrawal symptoms, nicotine replacement therapy and more. For high-risk members, get help by phone from a wellness coach and additional educational materials.

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

With regard to informing clinicians about services offered through VBID programs, plans can communicate the availability of services through the use of informatics and electronic medical records. Specific communications tools include:

- letters to prescribing physicians;
- general education of guidelines and health plan offerings;
- notification of member eligibility;
- continuing medical education (CME) courses;
- reminder systems for gaps in care, and
- promotion of coverage details, including codes to use for reimbursement.

In addition, health plans often offer incentives to physicians to encourage the use of appropriate services, including:

- incentives for conducting screening;
- incentives for program referral (e.g., education about a plan-sponsored smoking cessation program), and
- pay for performance by incorporating patient completion of preventive services as a component or factor in physician reward structure.

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?

Purchasers appreciate the need for consumers to be protected from potentially adverse consequences of a well-intentioned policy to encourage the appropriate use of preventive services. In particular, our members adhere to patient privacy regulations and appeals processes. Employers work with their vendors to ensure appropriate firewalls are in place to protect individuals' personal health information when collected by a third party.

As much as employers work to adhere to relevant privacy regulations, there are some inconsistencies in federal law that may complicate compliance. For example, plans and issuers must consider the requirements of the Genetic Information Non-discrimination Act (GINA) when information on a patient's familial risk is required to support access to expanded diagnostic services (e.g., family history of cardiac disease, colorectal cancer, or breast cancer). In order to protect patients from discrimination by insurers based on genetic inheritance, GINA generally does not allow insurers or health plan administrators to require patients to provide their genetic information or use it to determine coverage or rates. However, certain USPSTF services need family history information to select the right population for preventive treatments and services. Future regulations should consider implications for inclusion or exclusion of family history questions in health risk appraisals.

Comments Regarding Economic Analysis, Paperwork Reduction Act, and Regulatory Flexibility Act

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?

As noted above, PBGH has collaborated with Milliman with support from Sanofi-Aventis to define metrics to help quantify the impact of various value-based benefit design interventions. This report will soon be available on the PBGH website.

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?

[No comments to offer re: impact on policies, procedures, practice and disclosures.]

As a broad conclusion, the return on investment to employers for VBID shows promise to improve population health and potentially contain costs. However, these programs must be designed carefully and constantly evaluated to meet the unique needs of employers and their workforces to achieve these goals. For example, increased cost sharing for prescription

drugs across-the-board can reduce the use of necessary drugs and increase adverse medical events and associated hospital and medical costs. A more refined approach, recently detailed at Pitney Bowes,¹⁰ uses targeted reductions in patient cost sharing to encourage use of certain drugs by diabetics – and this approach was found to reduce the overall cost of treating these patients.

In other areas, a recent study by PBGH reached the following conclusions:¹¹

Health Promotion and Health Risk Reduction. There is widely accepted, strong evidence that unhealthy behaviors (e.g., smoking, poor diet, lack of physical exercise) are associated with the development of chronic disease, a principal source of the majority of health care spending today. There is also good evidence that health promotion programs can be effective in reducing risks for targeted populations and that risk reduction is associated with lower health care costs and reduced absenteeism.

Employers increasingly have included health promotion and risk reduction components in their health care benefit programs, perhaps more because of the strength of the evidence noted above than due to documented increases in value *per se*. The literature reviewed for this study uncovered wide variation in the extent to which specific behaviors are associated with health care costs and absenteeism and the effectiveness of specific programs in mitigating costs and absenteeism based on their design and the targeted behaviors or diseases.

Chronic Care Management. Growing recognition of the role of chronic disease in driving health care costs has increased attention to programs designed to better manage the care of chronic disease when it arises. Several recent reviews of the literature consistently concluded that disease management programs can improve clinical outcomes (i.e., “quality”), but there is inconsistent evidence regarding the effect of such programs on health care costs. As in the case of interventions designed to impede the development of chronic disease, disease management programs vary in their cost-effectiveness based on the conditions targeted and program design and setting.

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?

While HR Policy and PBGH primarily represent large employer organizations, considerations for small employers should include communication channels and HIPAA confidentiality issues that may make it more challenging for employer-initiated interventions vs. plan-initiated programs.

¹⁰ Mahoney, J, 2005, op cit.

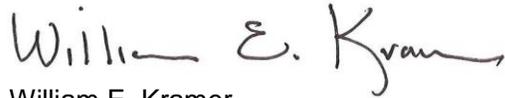
¹¹ Sandra Hunt, Susan Maerki and William Rosenberg, PricewaterhouseCoopers, LLP, Assessing Quality-Based Benefit Design, Prepared for the California HealthCare Foundation and Pacific Business Group on Health, April 2006 (Accessed at <http://www.pbgh.org/storage/documents/reports/PBGH-CHCFQualityBenDesignPWC-04-2006.pdf>)

We appreciate the opportunity to submit comments to this request for information. If you have any questions, please contact Marisa Milton at mmilton@hrpolicy.org or (202) 789-8671, or Bill Kramer at WKramer@pbgh.org, or 415-615-6317.

Sincerely,



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