February 28, 2011

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: HHS-OS-2010-002
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Submitted via: www.regulations.gov

Dear Sir/Madam:

America’s Health Insurance Plans (AHIP) is writing in response to the Request for Information (RFI) published in the Federal Register on December 28, 2010 regarding the use of value-based insurance design (VBID) in the coverage of recommended preventive services. The Affordable Care Act (ACA) requires health insurance plans to cover recommended preventive services without the imposition of cost-sharing. The ACA further recognizes that the Secretary of Health and Human Services (HHS), “may develop guidelines to permit a group health plan and a health insurance issuer . . . to utilize value-based insurance designs” in the provision of preventive care benefits.1

AHIP is the national association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of health insurance products in the commercial marketplace and have demonstrated a strong commitment to participation in public programs. AHIP’s member health insurance plans have pioneered innovative benefit designs that provide value and encourage delivery of quality health care. VBID uses research and clinical guidelines to promote better health, manage chronic conditions, and target populations with specific health needs and we appreciate the agencies’ recognition of the use of medical management techniques to help promote the use of evidence-based care and control costs.

We are responding to the specific questions in the RFI in the following discussion document. Our comments focus on the following key issues:

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1 ACA Section 1001 amending Public Health Service Act Section 2713.
• *How VBID Promotes Better Care by Linking Patients with Clinically-Appropriate Services* – A critical component of VBID is the use of incentives to encourage individuals to utilize preventive screenings, diagnostic testing, and other health services and treatments that have achieved desired health outcomes. VBID is designed to identify populations that would benefit from certain types of evidence-based, recommended preventive or other health services and help ensure individuals receive these services.

• *How VBID Features are Flexible and Innovative* – Health insurance plans and employers use a variety of VBID design features, including incentives, premium discounts, and copayment waivers or reductions, to encourage their members to engage in disease management, wellness programs, and other health improvement activities. VBID take a flexible approach and is rapidly evolving with the development of new clinical guidelines and outcomes research.

• *Why VBID Supports the Delivery of High Quality and Effective Care* – All stakeholders recognize that our healthcare system must provide better quality and more cost-effective care delivery. VBID supports these important goals by encouraging individuals to access critically needed, high-value services and health improvement activities. The ability of VBID to achieve high-quality and effective care should be promoted and recognized in the context of implementing other provisions of ACA, including essential health benefits.

• *Why VBID is Particularly Important in Supporting Access to Preventive Care* – The Interim Final Rule on Coverage of Preventive Services highlighted the benefits of access to preventive services with respect to improved health, lower health care costs, and increased productivity. VBID supports these goals through identifying individuals who would most benefit from recommended and often missed preventive services and encouraging use of quality care on a timely basis.

AHIP believes that VBID aligns with the national goals of improving patients’ health and overall health status and changing financial incentives in a way that drives quality and promotes consistency in health care delivery. We appreciate the opportunity to provide our comments on this important initiative.

Please feel free to contact me if you have any questions.

Sincerely,

Carmella Bocchino
Executive Vice President

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America’s Health Insurance Plans (AHIP) is writing in response to the Request for Information (RFI) published in the Federal Register on December 28, 2010 regarding the use of value-based insurance design (VBID) in the coverage of recommended preventive services.

Request for Information

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:

VBID uses a variety of approaches to identify patient populations and target incentives in a way that encourages individuals to access high quality care. Potential incentives may include one or more of the following:

- Using financial or other incentives for completing health risk assessments (HRAs).
- Waiving or reducing co-payments for certain classes of prescription drugs.
- Waiving or reducing cost-sharing for high performing providers.
- Waiving or reducing cost-sharing for certain types of medical treatments, tests or screenings.
- Providing incentives for reaching health targets, such as adherence with physician recommended medications.
- Waiving or reducing cost-sharing for particular settings of care (e.g., Centers of Excellence).
- Providing tools that help inform consumers about differences in treatment options and costs and sites of care.

These approaches are based on a number of factors, including an evaluation of what works best with a specific population, employer and individual choice in benefit design and coverage options, and clinical information and research on the effectiveness (i.e., the ability of an intervention to produce the desired result) and value of health care services. Flexibility in the use of these techniques allows plans to tailor the appropriate incentives to change consumer
behavior and encourage patients to use appropriate, high-value preventive services and health care providers.

We appreciate the recognition that VBID may include appropriate use of high-value settings of care.\(^3\) Not all network designs, however, should be considered within the context of VBID. For example, many plans provide access to in-network and out-of-network providers (e.g., Preferred Provider Organizations) and apply different levels of cost-sharing dependent on where consumers receive care, in-network or out-of-network.

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:**

Recent VBID programs have targeted populations with diseases that are preventable or can be managed including heart disease, hypertension, obesity, asthma, diabetes, and other chronic conditions.

VBID is typically structured for a specific population or health condition. Some current examples include the following:

- Encouraging patients with chronic hypertension to follow prescription therapies, such as ACE inhibitors and angiotensin receptor blockers, through a reduction or waiver of co-pays for these medications.
- Encouraging patients with diabetes to better manage their hemoglobin A1c levels by providing free blood glucose monitors.
- Encouraging patients with asthma or diabetes to follow prescription therapies by reducing or waiving co-payments for asthma and diabetes medications.
- Providing financial incentives for individuals who manage lifestyle or health conditions, such as tobacco use, high cholesterol or blood pressure levels, and blood sugar, and demonstrate improvement in addressing key factors that impact these conditions.
- Waiving co-payments for secondary prevention medications like statins for patients who have had a myocardial infarction.
- Offering incentives to encourage individuals to complete HRAs and worksite screenings or health improvement programs.
- Offering incentives to encourage individuals to meet physical activity and healthy eating goals.

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\(^3\) See: Affordable Care Act FAQ No. 1, December 22, 2010, accessed at: [http://www.hhs.gov/cciio/regulations/implementation_faq.html#FifthSetofFAQsIssuedDecember222010](http://www.hhs.gov/cciio/regulations/implementation_faq.html#FifthSetofFAQsIssuedDecember222010)
• Encouraging and supporting individuals who are participating in tobacco cessation programs by waiving co-payments for prescription medications.

In these types of approaches that encourage members (patients) to participate in health improvement-related programs or activities, VBID initiatives are voluntary.

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:

Although many of the VBID approaches are still in their early stages, there are a number of factors that are examined in determining “value.” A primary consideration is whether the service provides clinical benefits that are supported by high-quality evidence and provide value by producing improved health outcomes. Any cost savings associated with adherence to a particular medication therapy (e.g., prescription drugs used to treat diabetes) must be viewed in terms of the long-term improvement to the overall health of those individuals and not just the impact on the specific disease state. The ultimate goal of VBID is to improve the health of individuals by improving the care they receive.

For example, if an individual with heart disease participates in a VBID program, which reduces or eliminates cost-sharing for statins, the “value” of the VBID program is measured by whether that individual remains healthier over the long-term and avoids costly hospitalizations. VBID may increase costs and utilization in the short term, with the goal of improving health and decreasing the likelihood of long-term costly illness.

Plans evaluate VBID on an annual basis, using different data appropriate to gauging effectiveness for a population or a program. Plans may use patient or provider surveys, health screening information, claims data, and medication adherence information to determine if the patients participated in and received value from the program, whether positive health outcomes resulted, and what was the overall cost of the program.

Plans will generally track the clinical and financial impacts for the population over time to determine its “success.” Most data are created from internal sources or gathered by the plan through information collected from patient and provider surveys and analysis of the frequency
and utilization of health care services (e.g., preventive screenings, physician visits, prescription information, emergency room use, hospitalization, etc.). Plans may also receive information from employers (e.g., data regarding loss of days at work). In addition, new sources of data will greatly expand the effectiveness of VBID and the ability to closely track outcomes. For example, the development and adoption of electronic health records provide another valuable information source for evaluating the impact and effectiveness of VBID.

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:

Plans evaluate the overall impact of the incentive in reaching the stated goals of the benefit. In general, the plan is interested in determining: (a) the impact of an incentive on compliance or utilization (i.e., whether the individual accesses necessary services or programs, or follows a prescribed medication therapy) and (b) effectiveness (i.e., whether there is a positive impact on the individual’s specific condition and overall health).

As noted above, plans use a variety of information sources including surveys, claims data, prescription information, and results of screening and diagnostic tests.

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:

Plans typically evaluate plan design features on an annual basis, although the success or failure of a design is generally determined over the term of the contract period for employers or providers that have multi-year contracts (e.g., 2-3 years). Cost and quality information is obtained through claim and prescription data, surveys, and screening results. As noted, plans may use patient or provider surveys, health screening information, claims data, medication adherence information, and information from employer clients to determine if the patients participated in the program and whether there was a positive impact on the individual’s specific condition and overall health.
Effectiveness is measured through an evaluation of the impact of the VBID on the specific targeted condition, as well as individual health outcomes and the overall health outcomes for the population. Plans use a variety of measures, including participation, health outcomes, adherence to evidence-based clinical guidelines, productivity/absenteeism, and other factors. These metrics are based on standards developed by entities such as the National Quality Forum, National Committee on Quality Assurance, and others.

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:

Some plans are in the early stages of VBID while others have implemented these approaches and are improving them based on consumer feedback.

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

Response:

Plans will consider research and evidence-based clinical guidelines in evaluating whether VBID should be provided to a specific population. A plan may consider a number of factors in making this decision and designing the initiative, including the following:

- What are the health needs of the population?
- What types of VBID are of interest to employers?
- What do research and evidence-based clinical guidelines show with respect to specific treatment options?
- Based on recent research, are there different incentives that may have greater success?
- What is the most effective way to administer the benefit and track results?
- What available design options will promote consumer interest and engagement?

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:

Some VBID may identify specific groups within a population for participation based on health characteristics (e.g., presence of a co-morbidity) or that the individuals may need targeted incentives to encourage participation (e.g., individuals with heart disease who are not taking
prescribed medications). In circumstances where an individual is identified as being at-risk, he or she would be targeted with incentives to seek appropriate care, not with barriers to make care more costly.

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 data requirements will depend on the specific population, medical condition, and program design features. For example, a plan may use a health risk assessment or screening results to first determine which individuals would benefit from participation in a particular initiative. Assuming the individual agrees to participate in the program, data would be collected from various sources, based on the program operations and goals. A plan may, for example, review claims data to determine the overall health status of participants and whether their specific condition is being appropriately managed. Health plans have processes in place to protect the confidentiality of health information and to ensure personal data are used appropriately.

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:

Plans will review overall program design and outcomes to assess if all members of the identified population are receiving appropriate care, not just those members who voluntarily participate in the designated VBID.

In addition, plans typically have internal processes in place for patients and their treating health care providers to request alternative treatment goals based on clinically appropriate standards. Health plans also have exception processes in place that allow for coverage of higher-cost services if an individual’s treating physician provides a medical rationale specific to the patient. For example, a patient’s higher co-payment for a third tier drug could be reduced or waived if his/her physician provides the medical rationale as to why the third tier drug is preferred over lower cost alternatives.
Plans also meet state requirements and other standards with regard to network adequacy to ensure appropriate availability of the providers and facilities necessary to access these services within a given geographic area. Additionally, wellness programs are required to provide alternatives for individuals who cannot meet certain goals. For example, a provider may determine that an individual cannot reach a specific health target (such as a weight loss goal) due to medical reasons and will request the plan to designate an alternative goal.

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:

In addition to promoting access to recommended preventive health services, health plans use VBID to target different populations – individuals who are currently healthy (to encourage them to stay healthy), and people with certain risk factors or diagnosed with chronic conditions (to improve their health outcomes). Health risk assessments and administrative data, including claims, pharmacy, and lab data, are used by plans to identify individuals at risk. Strategies to improve the identified individual’s health outcomes include providing customized health action plans and appropriate chronic disease care plans and programs.

As mentioned earlier, frequent components of VBID include:

- Evidence-based recommended preventive health services;
- Tobacco cessation programs;
- Healthy weight/healthy eating programs;
- Physical activity goals;
- Medication compliance for patients with chronic conditions; and
- Reduction of health risks, such as high blood pressure, high cholesterol, and high blood sugar.

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

Response:

Plans inform individuals of the availability of and goals for the VBID, the requirements for participation, and the process for asking questions or resolving concerns or disputes. A variety of methods are used to inform individuals of the VBID and to make sure participants clearly understand the goals and requirements of these programs, including the following:

- Including information in state and federally required “explanations of coverage” and “standard plan documents” provided to prospective enrollees and on enrollment in coverage.
• Providing information about programs targeted to specific populations through plan newsletters, websites, phone calls to members, and other media.
• Working with employers to distribute information to employees and their family members.
• Providing information to physicians and other treating health care providers to share with their patients.

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

Response:

Plans use a number of distribution methods for physicians and other providers, including targeted communications, provider outreach, and newsletters. As with consumers, providers are informed about the program operation and goals, participation requirements, and process for resolving questions or concerns.

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:

Plans are subject to federal and state requirements guaranteeing access to recommended preventive care services and guarding against benefit features that may limit an individual’s ability to participate in a program. The ACA requires coverage for a broad range of designated preventive services without imposition of cost sharing. In addition, long-standing rules under the Health Insurance Portability and Affordability Act (HIPAA), which are incorporated into statute by the ACA, were put in place to protect consumers by placing certain limitations around the use of incentives for individuals participating in programs that require them to meet certain health-related targets (e.g., weight loss requirements).

State laws also require plans to provide patients with access to services and give regulators authority to investigate complaints where a particular benefit design or action by a plan may deny an individual’s ability to obtain appropriate care.

Additional rules are not necessary at this time. It is important that these approaches be allowed to be modified based on consumer input and not limit the flexibility of plans in designing the VBID. These programs are rapidly evolving as new evidence-based clinical guidelines and research becomes available.
In addition, to the extent that HHS chooses to issue new rulemaking, it should first publish the regulations in proposed form and give all affected stakeholders sufficient time to respond and suggest modifications, as necessary to carry out the VBID goals of improving health care quality.