February 28, 2011

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Attn: Office of Consumer Information and Insurance Oversight -- HHS-OS-2010-002

The Honorable Phyllis C. Borzi
Assistant Secretary
Employee Benefits Security Administration
U.S. Department of Labor
Attn: Office of Health Plan Standards and Compliance Assistance -- VBID

The Honorable Douglas H. Shulman
Commissioner
Internal Revenue Service
Attn: REG-120391-10 VBID

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

Dear Madam Secretary, Ms. Borzi, and Mr. Shulman:

Aetna welcomes the opportunity to respond to the Internal Revenue Service, Department of the Treasury, Department of Labor, and Department of Health and Human Services (collectively, "the Agencies") Request for Information ("RFI") regarding the use of value-based insurance design ("VBID") in the coverage of preventive services required to be provided free of cost-sharing by health plans under the Patient Protection and Affordable Care Act ("ACA"). *See* 75 Fed. Reg. 81544 (December 28, 2010).

Aetna is one of the nation's leading diversified health care benefits companies, providing members with information and resources to help them make better informed decisions about their health care. Our programs and services strive to improve the quality of health care while controlling rising employee benefits costs. Aetna offers a broad range of health insurance products and related services including medical, pharmacy, dental, behavioral health, group life, and disability plans and medical management capabilities.

Aetna appreciates that the interim final regulations regarding preventive care under the ACA do provide some flexibility with regard to VBID for preventive care services.[1] Going forward, however, Aetna also strongly requests that the Agencies not only retain this flexibility when additional guidance and/or final regulations are issued but *also* that they allow plans the flexibility to *create and add* new VBIDs related to preventive care – when such VBIDs are intended to add value and when protections are in place to ensure quality care.

Aetna has played an important role in providing preventive care services free of cost sharing to some of its patients for several years, well before being required to do so under the ACA. Moreover, Aetna has amassed useful information regarding such services -- particularly through its Aetna Health Fund consumer-driven product, for which it has publicly released findings since 2003.

Aetna's experience has been that VBID is critical to ensuring that patients receive proper preventive care, but without causing unreasonable and unnecessary costs to the plans – and, ultimately, to plan members. Without effective VBIDs in place, plans required to offer preventive care on a first-dollar basis are vulnerable to wasteful spending (which may result in an increase in premiums to participants) due to offering unnecessary and often expensive services. Moreover, effective VBID can also help doctors avoid performing needless procedures, and may also help reduce fraud and abuse.

The Agencies have requested information in several areas related to VBID, including specific VBID plan designs, measuring the quality of VBID, consumer protections, and safety valves in place for patient protection, as well as how VBIDs are communicated to plan participants.

This letter provides information and recommendations on each of these topics, drawn both from its specific experience with VBID programs (e.g., in its Aetna HealthFund® plan) and from it's more than a century of leadership in health care coverage and plan design.

I. Legal Background.

Section 2713 of the Public Health Service Act ("PHSA"), as added by the ACA, requires that a group health plan and health insurance issuer offering group or individual health insurance coverage provide benefits for – and prohibit the imposition of cost-sharing requirements with respect to – certain preventive services. The requirements to cover recommended preventive services do not apply to grandfathered health plans. The recommended preventive services include: (1) evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force ("Task Force") with respect to the individual involved; (2) immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee ("Advisory Committee") on Immunization Practices of the Centers for Disease Control and Prevention with respect to

[1] *See* 26 CFR 54.9815-2713T, 29 CFR 2590.715-2713, and 45 CFR 147.130 (75 Fed. Reg. 34538).

the individual involved; (3) with respect to infants, children and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration ("HRSA"); and (4) with respect to women, evidence-informed preventive care and screening provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force). 75 Fed. Reg. 41728. The recommended preventive services are subject to change as the recommendations are updated, but plans are not required to correspondingly change their coverage or cost-sharing until at least one year after such new preventive service recommendation or guideline goes into effect.

Plans have some flexibility under the current set of rules with regard to preventive care services, but more flexibility is necessary in order to continue steering participants to the services with the best value. Under the current rules:

- If the preventive service is billed separately from an office visit (or is tracked as individual encounter data separately), the plan may impose cost-sharing on the office visit, so long as no cost-sharing is imposed on the preventive service.
- Even if the office visit and preventive services are not billed separately (or are not tracked as individual encounter data separately), the plan must provide the office visit free of cost sharing only if the primary purpose of the office visit was the recommended preventive service.
- Plans do not have to cover preventive services on an out-of-network basis.
- If out-of-network preventive services are covered, they do not have to be offered free of cost-sharing.
- Plans are not required to cover or waive cost-sharing requirements for any item or service that is not listed as a required preventive service.
- Plans may choose to cover additional preventive care services (but are not listed as a recommended preventive service) with cost-sharing.

75 Fed. Reg. 41728-41729.

The interim final regulations also provide that if a recommendation or a guideline for a preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan may use reasonable medical management techniques to determine any coverage limitations. The use of reasonable medical management techniques allows plans to adapt the recommendations and guidelines for coverage of specific items and services where cost-sharing must be waived. Thus, a plan may rely on established techniques and the relevant evidence base to determine the frequency, method, treatment or setting for which a recommended preventive service will be available without cost-sharing requirements to the extent not specified in a recommendation or guideline. 75 Fed Reg. 41728 – 41729.

The Agencies recognized the importance of VBID in the preamble to the preventive care regulations. The preamble states:

> The Departments recognize the important role that value-based insurance design can play in promoting the use of appropriate preventive services. These interim final regulations, for example, permit plans and issuers to implement designs that seek to foster better quality and efficiency by allowing cost-sharing for recommended preventive services delivered on an out-of-network basis while eliminating cost-sharing for recommended preventive health services delivered on an in-network basis. The Departments are developing additional guidelines regarding the utilization of value-based insurance designs by group health plans and health insurance insurers with respect to preventive benefits. The Departments are seeking comments related to the development of such guidelines for value-based insurance designs that promote consumer choice or provide services that offer the best value and quality, while ensuring access to critical, evidence-based preventive services. 75 Fed Reg. 41729.

The Agencies also recently issued Frequently Asked Questions ("FAQs") regarding VBID, indicating that the Agencies will develop guidelines to permit health plans to utilize VBID. The FAQs define VBID as health plan designs that provide incentives for patients to utilize higher-value and/or higher-quality services or venues of care. *See* FAQs about Affordable Care Act Implementation Part V at http://www.dol.gov/ebsa/faqs/faq-aca5.html.

The FAQs also provide an example of a group health plan that does not impose a copayment for colorectal cancer preventive services when performed at an in-network ambulatory surgery center. In contrast, the same preventive services provided at an in-network outpatient hospital setting generally would require a $150 copayment. The FAQs make clear that this arrangement is permissible, recognizing that plans may use reasonable medical management techniques to steer patients toward a particular high-value setting (like an ambulatory care setting), 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 the hospital. Aetna is appreciative of this guidance permitting this useful VBID.

II. Aetna Requests Favorable and Flexible Guidance on VBIDs in Connection with Recommended Preventive Services.

VBID is critical to developing and offering products that comply with the preventive care regulations but also maximize value and quality of care, while minimizing costs to plans and patients. It is Aetna's goal to work closely with the Agencies to establish preventive care guidelines that promote flexibility with regard to VBID that will encourage quality of care, without adding undue costs for plans and patients.

Retain Current Flexibility. First and foremost, as the Agencies finalize the preventive care regulations and issue additional guidance under the ACA, Aetna requests

that the current flexibility that is permitted for VBID under the interim final regulations be maintained. Without VBID, consumers could be faced with unnecessary cost and subjected to needless and wasteful services. Plans with VBIDs create value by incentivizing participants to take advantage of high-value, clinically effective, evidence-based preventive care services, and by discouraging their participants from undergoing duplicative and avoidable procedures. For example, plans encourage participants to visit in-network providers (whose performance and quality of care are monitored closely by the carrier) by eliminating co-pays for in-network providers while maintaining co-pays for out-of-network providers (whose performance is not monitored by the plan). This VBID design (and others) are permitted under the current rules, and should not be limited in future guidance.

Under the current rules, plans also may use reasonable medical management techniques for recommended preventive services, such as frequency, method, and treatment limitations. In other words, through medical management, plans may discourage members from seeking duplicative procedures and examinations by limiting the frequency of doctor visits and services. To that end, Aetna seeks clarification that a plan may, by design, limit the number of office visits at which a participant may receive preventive care services free of cost share. For example, a plan should be permitted to limit participants to one preventive office visit per year at which the participant may receive a majority of the more routine preventive services required under the rules (e.g., immunizations and screening for depression). More intensive preventive services (e.g., colonoscopy or ongoing nutritional counseling for obesity) would be provided at special office visits that also would be provided free of cost share.

Flexibility to Create New VBIDs. Additional flexibility should be provided in future guidance that will provide plans the freedom to design new VBIDs. Any restrictions on future designs would prevent plans from creating the most valuable product for patients. Plans will have better capability to work with medical data as progress is made in health information technology, which will position plans to develop new VBIDs. To discourage plans from developing new VBIDs would be detrimental for participants and the health care system in general because plans are in the best position to understand how to maximize value for the participants.

Special Issues Regarding Preventive Care Drugs. The Economic Impact Section of the preamble to the interim final preventive care regulations suggests that only physician counseling regarding an over-the-counter medication or vitamin must be offered free of cost-sharing, rather than the over-the-counter medication itself. *See* 75 Fed Reg. at 41731. As a result, many plans have interpreted the preventive care recommendations regarding over-the-counter medications or vitamins (e.g., aspirin and folic acid) as not requiring the medication or vitamin to be provided free of cost-sharing. Aetna seeks clarification that a plan is not required to provide specific over-the-counter medication or vitamins free of cost sharing – merely the doctor's service counseling the patient and ordering the over-the-counter medication. In the event that guidance is issued, requiring the actual medication be provided without cost sharing, Aetna requests that such guidance be prospective only, given the contradictory language in the preamble

to the interim final regulations. Requiring coverage of these over-the-counter medications will increase administrative costs, as well as benefit costs.

Additionally, as required by the ACA, over-the-counter medications covered by group health plans are taxable unless prescribed, as required under state law. Internal Revenue Code Section 106(f). Aetna seeks guidance clarifying that, to the extent plans provide over-the-counter medications as preventive care, plans may limit the over-the-counter medications that are covered to those that are prescribed as required under state law.

Finally, Aetna seeks clarification that preventive care medications required by the preventive care regulations can always be provided under a high-deductible health plan, as defined under Section 223(c)(2)(c) of the Internal Revenue Code, without impacting a participant's eligibility for a health savings account. IRS and Treasury have provided a safe harbor definition of preventive care under IRS Notice 2004-23 and IRS Notice 2005-50. In Q&A-27 of Notice 2004-50, IRS indicated that drugs or medications may be preventive care when taken by a person who has developed risk factors for a disease that has not yet manifested itself or not yet become clinically apparent, or to prevent the reoccurrence of a disease from which a person has recovered. In addition, drugs used as part of procedures listed in Notice 2004-23, including obesity weight-loss and tobacco cessation programs, are also considered preventive care for these purposes. The preventive care safe harbor under Code Section 223(c)(2)(c) does not include any service or benefit intended to treat an existing illness, injury or condition, including drugs or medications used to treat an existing illness, injury or condition. There may be circumstances when the drugs or medications listed in the recommendations are also used to treat an existing illness, injury or condition (e.g., aspirin may be used as a pain killer). Aetna is requesting guidance that any drug or medication listed in the preventive care recommendations should be permitted to be offered on a first-dollar basis before the deductible is met under a high-deductible health plan without making participants ineligible for health savings accounts.

III. Information Requested by the Agencies.

The Agencies have requested information in several areas related to VBID, including specific plan designs that are offered, measuring quality of VBID, consumer protections and safety valves in place for patient protection, as well as how VBIDs are communicated to plan participants. Aetna provides information on these topics below that should be useful to the Agencies.

A. Aetna's Specific VBIDs.

Aetna has taken specific measures to incorporate VBID within its health plans with regard to preventive care services, including through medical management, incentives for participants receiving preventive care services, limits on providers, prescription drug programs, and by offering consumer-driven health plans.

Medical Management. Aetna uses various medical management techniques (such as the precertification of certain services) to ensure that those services are adequate and appropriate for its consumers. Additionally, Aetna reviews services and treatments after they are provided for medical necessity. As permitted under the preventive care rules, Aetna has relied on established techniques and the relevant evidence base to determine the frequency of certain preventive care services (e.g., the number of obesity counseling sessions.) Aetna offers a disease management program which provides guidance to participants on the appropriate services and treatments they should obtain for a particular illness or condition for which participants may be at risk. The Aetna Health Connections Disease Management Program provides active monitoring with nurse engagement for participants with certain conditions (e.g., diabetes). Aetna also offers a special disease management program provided for maternity care. Finally, Aetna administers coaching to help participants make the decisions to promote a healthy lifestyle, such as weight management and smoking cessation coaching.

As discussed above, Aetna is considering requiring participants to receive multiple, routine preventive care services at the same visit, and requests guidance permitting this VBID approach. This will improve quality by integrating health care services into one visit and prevents an unbundling of services which creates additional expense without improving quality. Finally, Aetna has opted to impose cost-sharing on out-of-network preventive care services, as permitted under the interim final regulations. Such steps have proven effective in driving better coordination of care.

Incentives for Participation in Wellness Programs. Aetna's Healthy Action Programs, and supporting incentives, help plan sponsors to reward employees for adopting healthier behaviors, including obtaining preventive care services. The most popular incentives are tied to completion of health risk assessments and online wellness completions. Growing in popularity are incentives tied to preventive care and participation in disease management. Aetna Healthy Actions provides tracking of selected activities for participant engagement and to support plan sponsors' administration of rewards. Typical rewards include health reimbursement arrangement or health savings account contributions, deductible and/or coinsurance offsets, gift certificates or gift cards, merchandise, premium reductions and paid time off.

Limits on Providers. In some cases, it is beneficial for Aetna to limit the number of service providers available under the plan for certain treatments, such as smoking cessation. Aetna determines, based on clinical studies and evidence, the providers that are preferred for these purposes, and may provide preventive care services under the plans free of cost sharing only when these providers are utilized. By limiting its vendors, Aetna has better bargaining power to reduce treatment costs, which saves the plans money overall.

Prescription Drugs. Aetna offers a preventive medication feature for members enrolled in Aetna's consumer-directed plans. This feature reduces member liability for prescription drug expenses by waiving the deductible and applying underlying plan features to certain drugs that Aetna has determined are preventive in nature.

Additionally, Aetna has waived the co-pay on certain high-impact drugs (e.g., diabetes drugs and asthma drugs). The purpose of waiving the co-pay for these high-impact drugs is to maximize their use in combating particularly devastating and costly conditions, thereby resulting in overall savings and better health per member, as well as benefitting employers through reduced absenteeism for employees.

Aetna also uses a tiered network approach to prescription drugs by designating the lowest co-pays to generic medications. Meanwhile, where generally accepted standards for clinical effectiveness are not met, Aetna applies limitations to coverage of such drugs. For example, Aetna limits coverage on the number of fertility treatments, because after a certain number of attempts the likelihood of success drops. Aetna may require lab or genetic testing before certain drugs are covered because some drugs have been shown to be ineffective for individuals with certain genetic characteristics.

Consumer-Driven Plans. The insurance industry has already recognized the importance of consumer-engagement in VBID, and Aetna has entered this market through the promotion of cafeteria plans, health flexible spending accounts, health reimbursement arrangements, and health spending accounts. These plans combine health plans with consumer-controlled accounts and incentivize consumers to consider the cost of treatments because the consumer can use the money he or she saves for future or other medical expenses. More specifically, Aetna's HealthFund combines the protection of a traditional health plan with an employer-paid health fund and grants consumers the freedom to choose referral-free access to an expansive network of discounted physicians and hospitals, as well as the ability to seek out-of-network care at a higher out-of-pocket cost. Aetna understands that the value of consumer choice is lost if the consumers have no way to navigate through their options and choose the plan that best fits their needs. With this in mind, Aetna provides educational tools that will help individuals estimate expected costs by evaluating their past expenses and estimating their future expenses.

B. Measuring Quality.

Aetna places great importance on measuring quality in all of its VBID programs, as discussed below.

Clinical Evidence. Aetna relies on clinical evidence during the medical management process to ensure that there is adequate proof that a planned therapeutic intervention will work to cure or mitigate a condition before Aetna approves coverage. Historically, if the evidence suggested medical efficacy, Aetna will cover a procedure, test or medication but if the evidence was insufficient, Aetna does not cover the procedure. Aetna's Clinical Policy Bulletins ("CPB") are the best example of Aetna's process with regard to coverage practices and evidence-based insurance designs. Aetna makes this information available to the public on www.aetna.com. Of course, Aetna is covering the recommended preventive care services required under the interim final regulations.

Additionally, Aetna reevaluates data of its services annually. While the first priority is always quality of care, Aetna will consider return on investment when deciding whether or not to continue a particular VBID. After evaluating data, Aetna often finds that certain health benefits offer less value for participants than originally thought. In such instances, Aetna will potentially remove or amend a particular VBID method.

Program Studies. After Aetna implements a new plan or significant new plan design, it follows up on its effectiveness. Aetna historically has waived cost-share requirements for preventive care in high-deductible health plans ("HDHPs") to encourage participants of HDHPs to seek preventive care services. Aetna has engaged in a seven-year study to determine whether participants in HDHPs received comparable preventive care services to those participants in a PPO plan. The result of the survey was that participants of HDHPs received preventive care services as frequently as participants of PPOs. Since the results were considered favorable, Aetna continued to provide preventive services free of cost-sharing in its HDHPs.

Aetna has released some of its studies to the public to further facilitate consumer engagement. Since 2003, Aetna has released its studies about the Aetna HealthFund. Most recently, the study was based on 707,000 Aetna HealthFund members that were continuously enrolled for 18 months and who were compared to similar PPO members. The results for the financial part of the study are based on 135 plan sponsors that offer an Aetna HealthFund plan and represent 2.3 million Aetna members (498,000 Aetna HealthFund members plus 1.8 million members who had the option of selecting Aetna HealthFund, but chose another product). The study results indicate that savings are generated without shifting preventive care costs to health plan members.

Pharmaceuticals. Aetna's National Pharmacy and Therapeutics ("P&T") Committee takes a lead role in the development of Aetna's formularies. One of the Committee's responsibilities is to review clinical effectiveness based on the available clinical literature to help determine formulary placement of particular drugs. For example, Aetna has cost-sharing tiered plan designs that use lower copayments to encourage the use of clinically appropriate and cost-effective generic drugs or ordering drugs through the mail, as well as a complete waiver of copays for high-impact drugs (e.g., drugs for asthma or diabetes). In addition, Aetna continually reviews classes of drugs to help maintain access to benefits that promote cost-conscious and clinically appropriate therapy.

Health Information Technology. The process of identifying such information is complex and continues to evolve. Therefore, Aetna is always investing in better health information technology to improve its ability to identify personalized data regarding which people are high risk for certain diseases/illnesses. It is anticipated that as health information technology improves, new and more tailored VBIDs will be created.

C. Consumer Protections, Mechanisms and Safety Valves with Regard to VBID.

Aetna already has various protections in place to ensure its participants receive quality care. Some of the many examples include Aetna's accreditation requirements to ensure that its participants have access to adequate in-network providers; a Rx Check program to encourage members to maximize the value of their prescription drug benefits; an internal and external appeals process as required by the rules under ERISA and the ACA; and a Care Engine program which scans personal health records and then provides alerts and recommendations to physicians so that they provide the best care to their patients. Aetna's Care Engine is particularly worth noting because it can identify fatal drug interactions in the case of a member who has multiple prescriptions and treatments that can mitigate potential long-term side effects of prescription drugs. It also helps to identify alternative treatments in instances where the customary treatment is not the most effective health service for a minority of the population.

D. Communicating VBIDs.

Since Aetna believes that VBID is most effective when Aetna participants are engaged (in order to appreciate the value of the services offered), Aetna takes many steps to inform its consumers about the VBID features in its health coverage. Therefore, in addition to providing descriptions of these programs in summary plan descriptions, newsletters, mailings and other traditional marketing materials, Aetna also uses a variety of communication avenues that are more likely to get consumer attention, such as emails, websites and other social media. Aetna is exploring additional opportunities to better inform its consumers. For instance, eventually Aetna would like to inform physicians and providers about VBIDs through electronic medical records with "prompts" regarding the various VBIDs.

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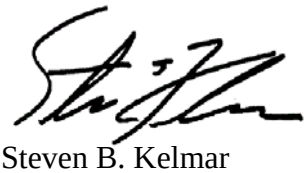
Aetna is pleased to have the opportunity to provide comments regarding VBID. Thank you for considering our comments. Should you have any questions, please feel free to contact me.

Sincerely,



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