

February 28, 2011

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

U.S. Department of Health and Human Services
Office of Consumer Information and Insurance Oversight
Hubert H. Humphrey Building
200 Independence Ave., SW
Room 445-G
Washington, DC 20201

U.S. Department of Treasury
Internal Revenue Services
1111 Constitution Ave., NW
Washington, DC 20224

RE: File Code: HHS-OS-2010-002, Request for Information Regarding Value-Based Insurance Design with Preventive Care Benefits

Submitted electronically to US Department of Health and Human Services: www.regulations.gov

To Whom It May Concern:

Families USA is a national nonprofit, nonpartisan organization dedicated to the achievement of high-quality, affordable health coverage for all. We are writing in response to the Request for Information Regarding Value-Based Insurance Design with Preventive Care Benefits issued December 28, 2010, Federal Register, Vol. 75, No. 248, File Code HHS-OS-2010-002. We appreciate the opportunity to provide these comments. We first provide general comments on value-based insurance design. We then respond to the agencies' questions below.

Any value-based insurance design (VBID), whether for preventive services only or also for treatments, must be required to include certain basic elements, including:

- 1.) Use of evidence-based quality measures for health care services and providers when determining what/who is a high value or low-value service or provider,
- 2.) Adequate and meaningful access to health care providers at \$0 cost sharing for preventive services,
- 3.) Accurate and easy to understand education materials for consumers *and providers* on what value-based insurance design is, how it works, and implications for patients and information and decision-support tools on high-value and low-value services and providers,
- 4.) Beneficiary protections, including an exceptions and appeals process for access to \$0 cost sharing for health care services and access to providers at \$0 cost-sharing levels,
- 5.) Evaluation process of value-based insurance design on patient access to care, financial implications for patients, and impact on patient populations, particularly vulnerable populations.

Regulations on value-based insurance design must ensure that VBID is not used to increase costs to beneficiaries or limit their access to medically necessary health care services and providers.

We ask that the agencies clearly define value-based insurance design to ensure that coverage and cost-sharing decisions are based on quality and cost (i.e. value) and not cost alone. The agencies should provide guidance and examples of what does and does *not* constitute value-based insurance design.

We also ask that the agencies define “reasonable medical management techniques” and provide guidance and examples of what would and would not be considered acceptable “reasonable medical management techniques.”

Value-based insurance design has the potential to lower costs, improve health care quality, and improve patient health, and can complement other strategies within the Affordable Care Act. However, if not done properly, value-based insurance design could improperly limit patient access to providers and needed health care services. Any value-based insurance design must be structured in a way that keeps in mind that many consumers currently lack knowledge about the value of health care services and providers and the ability to make informed decisions about their health care (i.e. knowledge gap), as well as the structure of our current health care system, which includes a significant shortage of primary care providers.

We thank you for considering our comments. If you have any questions or require additional information, please contact Michealle Gady, Health Policy Analyst, at 202-626-0633 or mgady@familiesusa.org.

Sincerely,

Michealle Gady
Health Policy Analyst
Families USA

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)? How is effective defined?

Plans have used a variety of mechanisms to direct beneficiaries to providers and to influence patient behavior, including, but not limited to:

- a.) Higher or lower cost sharing or waiving cost-sharing for services and/or providers
- b.) Premium increases or decreases
- c.) Higher or lower deductibles or waiving deductibles
- d.) Financial rewards, including contributions to health savings accounts, cash awards, gift cards, etc.
- e.) Limiting provider networks in exchange for lower premiums
- f.) Financial incentives to use Centers for Excellence for certain health care services

Studies have shown that higher premiums and cost sharing have not incentivized consumers to seek high-value services or providers. Instead, these higher out-of-pocket costs have led beneficiaries to delay accessing health care, which can lead to higher medical expenditures because of emergency department utilization and in-patient hospitalization.¹

We recommend that plans be required to study and publicly report on the effectiveness of any incentive program that they implement as part of a value-based insurance design. It is important to have a better understanding of what approaches are effective in directing beneficiaries to high-value health care services and providers.

Value-based insurance design through lower cost-sharing for high-value services can increase access to these services, improving the health of patients and leading to the delivery of more cost-effective care. However, beneficiaries do not currently have access to information and/or lack the ability to use such information to make decisions, on their own, about what constitutes a high-value or a low-value service. Decisions about what services a beneficiary receives are often made exclusively by the provider, who may or may not know whether a service or provider is a high- or low-value.

Rather than rely exclusively on financial incentives or disincentives to steer beneficiaries to high-value services and providers, we recommend that plans also provide beneficiaries with accurate, and easy to understand information about specific services and what makes them high-value or low-value. We also recommend that plans provide beneficiaries access to health care decision-support tools to help them use the information that they have access to in making a decision about whether a specific service is right for them.

Plans also use financial incentives or disincentives to steer beneficiaries to certain providers (ex. In-network v. out-of-network providers). We support efforts to direct patients to high-quality providers. However, plans must be required to ensure that beneficiaries have access to an adequate network of high-quality providers (i.e. providers accepting new patients, no undue wait times, etc). If a plan uses financial incentives to direct beneficiaries to certain providers, they should do so based on quality measures and costs. We recommend that plans use and publicly

¹ Swartz, Katherine, *Cost-Sharing: Effects on Spending and Outcomes*, Robert Wood Johnson Foundation, The Synthesis Project, December 2010, available at www.policysynthesis.org.

report quality measures when designing networks and provide information to beneficiaries explaining how the plan determines who is a high-value provider.

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)?

Fendrick, *et al* describe four basic approaches to value-based insurance design.² We are greatly concerned about plans utilizing the fourth approach – Design by Disease Management Participation. In this approach, a beneficiary would receive the lower cost-sharing for preventive services only if they also participate in a disease management program or wellness program. For example, a beneficiary would receive screening and counseling for obesity at \$0 cost-sharing only if they also participate in weight loss wellness program. There are many reasons why a beneficiary might be unable to participate in such a program, such as a physical disability or the expense associated with being away from work or their children. Limiting access to the benefit of \$0 cost-sharing for preventive services only to those beneficiaries who participate in such programs is contrary to the intent of the law, which is to maximize the use of preventive services, and in the best interest of the consumer's health.

Further, we have concerns about the effectiveness of many wellness programs and their impact on access to care for consumers and particularly those with lower incomes. Families USA expressed these concerns in a January 31, 2011 letter to the Departments and through participation in the Open Door Forum on wellness incentive programs held by the Departments on February 24, 2011.

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?

When determining what is a high-value or a low-value treatment or who is a high-value provider, a plan must be required to always use quality as an indicator and not cost alone. Some employers and insurers have argued that the use of reference based pricing is a form of value-based insurance design. For example, Cigna, in its comments on the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, described a reference based pricing design as an example of value-based insurance design in which a plan caps reimbursement for a colonoscopy at \$800. If a patient receives a colonoscopy from a provider for \$800 or less, the beneficiary has no cost sharing. If, however, the provider charges more than \$800, the beneficiary must pay the difference, regardless of whether the provider is in-network or out-of-network. Safeway, the retail grocery, uses a similar design for its employees, capping reimbursement for a colonoscopy at \$1500 and in its comments on the same interim final rule also categorizes this approach as value-based insurance design. However, we request that the agency clarify in rulemaking that any reimbursement structures must assure that high-quality services are available and accessible at a particular cost. If the decision to cap reimbursement is based only on cost, it is not value-based insurance design and the regulations must explicitly clarify this.

²Fendrick, M.; Chernew, M.; and Levi, G., *Value-Based Insurance Design: Embracing Value Over Cost Alone*, The American Journal of Managed Care, Vol. 15, No. 10, December 2009.

To be clear, we fully support benefit designs that lower costs to consumers and improve their access to high quality care. However, we do not support shifting costs to beneficiaries or limiting access to care or providers based solely on cost.

When determining what is a high-value or low-value service or provider, plans should use evidence-based studies and/or clinical process and outcomes measures. Plans must be required to disclose which data they rely on when making value and coverage decisions and provide an explanation if the plan's decision in anyway departs from the data.

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?

When plans determine which incentive models and/or amounts in steering patients toward high-value and/or amounts in steering consumers towards services or providers, they must be required to take into consideration the health, cultural and linguistic needs, socio-economic status, geographic distribution of providers, and ease of access to services and providers of the patient population and of the individual patient.

Plans should also be required to take into consideration the value of the service or health care provider to the patient. In some cases, what is considered a low-value service for the general population may be the only appropriate option for an individual patient. In this case, the patient should have access to the lower cost sharing or other incentive.

5.) How often do plans and issuers reevaluate 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)?

Plans should evaluate the impact of the value-based insurance design on beneficiary access to care, utilization rates, the beneficiary experience with accessing health care services under the value-based insurance design, and the financial impact on the beneficiary. Such an evaluation should be done by patient populations, with a particular focus on vulnerable populations. This evaluation should be conducted annually. Plans should be required to use this data when making decisions about how to adjust value-based insurance design options.

We also recommend that the agencies conduct independent evaluations of value-based insurance designs and report the findings publicly.

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?

A plan should be required to conduct an evidence-based analysis at a population level when determining whether to adopt a new VBID method or to continue an existing VBID method. If such an analysis shows a negative impact on a particular patient population, the plan should not adopt that method or, if already in use, should discontinue the VBID method for that patient population. consider continuation of the VBID method for that patient population.

Plans should only be permitted to make changes that would increase cost sharing when they have provided notice during an open enrollment period or prior to the beginning of the plan year. If a plan decides to adopt a new method or discontinue an existing VBID method, it must be required to communicate this decision and provide an easy to understand explanation to consumers.

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

Plans must be required to consider research and evidence-based guidelines, not just cost, when evaluating whether a new or additional preventive care benefit or treatment should be adopted as part of its VBID. The plan should also take into consideration the impact on the patient population.

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)?

The goal of VBID should be to facilitate the patient receiving the right care, at the right time, in the right setting. Not all preventive services are right for every patient, as is indicated by some recommendations from the United States Preventive Services Task Force. However, VBID should not be used to improperly limit access to services. When making a determination about different cost-sharing requirements for the same service based on population characteristics, plans must be required to use evidence-based clinically appropriate guidelines.

Plans should also be required to analyze the impact of such cost-sharing structures on low-income populations. Low-income populations are negatively impacted by cost-sharing structures that increase their out-of-pocket expenditures. A seemingly nominal increase in cost-sharing amounts can cause lower-income individuals to decrease use of needed services, resulting in adverse health outcomes, since such expenditures consume a greater percentage of their incomes. Regulations must ensure that approved VBID models do not result in unintended consequences for low-income populations.

Plans must also be required to take into consideration the patient's access to certain types of services and provider settings. For example, a patient at high risk for breast cancer may not have access to an in-network provider that provides BRCA genetic testing. This screening can help the patient determine what other screenings and/or treatments she should consider to minimize her risk of cancer. In such a case, the patient should still be able to access the screening at \$0 cost-sharing and any other appropriate services based on her at-risk status.

Additionally, for some patients, the "low-value" service may be the only medically appropriate service. In such a case, the patient should have access to the service at the same cost-sharing as the alternative "high-value" service.

While some of the USPSTF recommendations address screening for at-risk populations, not all of the recommendations do, particularly with respect to frequency of screening. In such cases, the agencies have said that plans will use reasonable medical management techniques to make determinations of coverage. We ask that the agencies define reasonable medical management techniques and provide guidance on what is and is not considered a reasonable medical

management technique. In making determinations of at-risk status, plans should rely on evidence-based clinical guidelines and studies. The plan must be required to also give great weight to the patient's provider's judgment.

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?

Plans should be required to collect and report both to the agencies and on the plan website: demographic information and the patient population in the VBID, the value of incentives used and what format they are administered in (high or lower cost-sharing, reward versus penalty, etc.), a description of the types of information and decision-making supports the plan provides to beneficiaries to help them make informed decisions about services and providers, the amount of savings to the plan, the impact of the VBID on premiums, cost-sharing, and utilization, the impact on beneficiary health and access to care, and an evaluation of beneficiary experience and satisfaction with the VBID.

Data collection should be done in compliance with the Americans with Disabilities Act, the Genetic Information Non-discrimination Act, the Health Insurance Portability and Accountability Act, and the Civil Rights Act.

The public reporting of this data will not only allow for monitoring to catch any adverse impacts, but will also inform the VBID research to develop good models that improve beneficiary health and lower health care costs.

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?

The VBID regulations must require that plans provide an easily accessible exceptions process to ensure that beneficiaries can access the medically appropriate preventive services that they need at \$0 cost-sharing. Plans must be required to communicate the availability of such an exceptions process in plan documents, such as the Evidence of Coverage, Annual Notice of Change, on their website, on Explanations of Benefits, and other appropriate beneficiary communications.

It is important that plans also ensure that communities facing disparities maintain access to culturally competent providers and settings with \$0 cost sharing.

An easily accessible exceptions process must be in place for patients for whom a "high-value" service will not be effective or is contraindicated. If the consumer is able to demonstrate the medical necessity of an alternative screening, the plan must be required to cover the service at \$0 cost-sharing.

See question 14 for a more detailed explanation of how the exceptions process should work.

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

Plans may wish to couple VBID for preventive services with wellness programs. As discussed previously, we have many concerns about such an approach, particularly if a consumer will only receive the benefits of VBID if they participate in a wellness program. We are particularly concerned about the impact of wellness programs on low-income people. Low-income people are at a disadvantage in wellness programs that use penalties or rewards, whether they are based on actual health changes (blood pressure, weight, etc) or just on participation. This is true for two reasons: First, low-income Americans are more likely to have the health conditions that so-called wellness plans target and are, therefore, more likely to be affected by any disincentives or penalties imposed by the wellness program. Second, barriers to healthy living – a lack of affordable healthy foods and safe exercise spaces in low-income neighborhoods – and the expense entailed in taking time away from work or children, can make it difficult for low-income people to participate in wellness programs. Penalties for failure to participate in or meet the goals of a wellness program also disproportionately affect ethnic minorities who disproportionately suffer from hypertension, diabetes, and other conditions wellness programs target. Finally, people with mental illness or disabilities may be unable to meet wellness goals for medical reasons.

Since it is particularly important that these populations receive the benefits of preventive screening services, we do not support tying participation in wellness programs to receiving the benefit of VBID for preventive services. Regulations should clarify that wellness programs, such as those that incentive people to achieve health outcomes, are not a form of VBID.

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

Value-based insurance design is a new type of insurance that consumers are not familiar with. To ensure the success of VBID, plans should engage in outreach to enrollees. Plans must be required to communicate with consumers in a variety of ways, including through plan documents such as Annual Notice of Coverage and separate communications specifically about VBID provided through plan newsletters, emails, and websites, and toll-free hotlines staffed by customer service representatives that can answer questions about the consumers VBID. These communications must be accurate and easy to understand. They must explain what VBID is, how it works, the patient's rights and responsibilities, the provider's rights and responsibilities, what services are covered, what providers are covered, what decision-making supports the plan provides and how the beneficiary can access them, and what exceptions and appeals processes are available and how to access them.

Value-based insurance design assumes that patients can distinguish between a high-value or low-value service or provider and will respond accordingly. The evidence is strong that this is not the case for most patients.³ Even if patients have access to information about a service or a provider, it does not mean that they will have the ability to understand it and use it to make an informed decision. It will be important that plans provide beneficiaries with information that provides them with an understanding of the screenings available to them. Plans should also provide beneficiaries with decision-making supports that will allow them to determine if there are alternatives to the screening recommended by their provider. These support tools should clearly explain to them what their financial responsibilities will be for each type of screening and /or provider. If the

³ *Id* at 1

beneficiary is not eligible for coverage for a particular service, the support tool should explain why and should provide information to the beneficiary about how to request coverage if the patient believes he or she should have access to the service or provider.

Any communication with consumers must be done in a culturally and linguistically appropriate format. Consumers must be able to access information about VBID in their choice of language, whether that is through printed materials, a website, or through a telephone hotline.

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

Value-based insurance design also assumes that providers know whether a service or provider is high-value or low-value or when it is appropriate for a patient to receive a particular preventive services screening. This is not always the case. Because patients will rely heavily on the recommendation of their provider, even with decision-support tools available to them, it is vital that plans educate providers about not only value-based insurance design, but also about recommendations for preventive services and which facilities or providers are considered high-value or low-value. One approach plans could take would be to notify a provider when the provider's recommended service is not considered a high-value service by the plan and tell the provider what service the plan does consider to be high-value

Plans will need to determine the most effective ways to communicate with providers and implement a robust education process for providers, including information on how providers can help their patients obtain exceptions when they require services or care from providers that the plan does not consider to be high-value.

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 §2713?

In addition to accurate, easy to understand information about VBID and access to decision-making support tools, beneficiaries must also have access to a reasonable exceptions process and a reasonable appeals process both for services and providers. Regulations must require that plans provide beneficiaries access to exceptions and appeals processes.

If a provider recommends a screening to a patient that is not considered a "high-value" screening or if the provider recommends a screening but the plan determines that the patient does not meet the plan's criteria for \$0 cost-sharing, then the patient should be able to access an exceptions process that allows him or her to demonstrate that he or she should receive the screening recommended by the provider at \$0 cost-sharing.

The process should be easily accessible and should not be overly burdensome (i.e. requirements to complete specific forms). Such a process could follow the model of the Medicare Part D tier or formulary exceptions process, as described in Chapter 18 of the Medicare Part D Manual. In this model, a provider submits a statement, either oral or written, that supports the beneficiary's need for the screening in question. If the provider and/or beneficiary choose, they can submit additional supporting evidence, such as scientific studies and evidence-based clinical guidelines. In such cases, the plan must be required to allow the provider or beneficiary to submit such evidence. Plans should be required to evaluate and consider this additional evidence. If the beneficiary demonstrates that the "high-value" service for which the plan would provide full coverage would

not be as effective or is contraindicated or that he or she is at high-risk for the condition and in need of the screening, the plan must be required to provide \$0 cost-sharing for the screening recommended by the provider. If the plan denies the exception, then any further internal and external appeals processes must be available to the beneficiary.

If plans are permitted to pursue a “tiered” provider network, in which consumers would have a tiered cost sharing structure for preventive services based on the quality of the provider they see, plans must be required to ensure that beneficiaries continue to have meaningful access to \$0 cost sharing. This would require that plans not only ensure an appropriate number of providers in a geographic area, but also that those providers accept new patients, can meet the cultural and linguistic needs of the patient, is easily accessed by public transportation for those who rely on such transportation, and that the providers appointment hours are accessible by the patient. If a patient cannot meaningfully access an in-network provider at \$0 cost-sharing, the plan must be required to provide the consumer with an exception and allow the consumer to pay \$0 cost-sharing at an out-of-network provider. Additionally, if there are no providers in the \$0 cost sharing tier that provide a particular preventive screening, the beneficiary must have access to this service at \$0 cost sharing through a different tier provider.

These same protections should be in place for beneficiaries who need to see an out-of-network provider. There are legitimate reasons when a consumer must access an out-of-network provider and should be able to do so at \$0 cost-sharing. For example, if a consumer is unable to find any in-network providers who are accepting new patients or if there are no in-network providers that provide the preventive service. One consumer that we have been contacted by has been diagnosed with Crohn’s disease. Her condition is particularly complicated. Because of the extraordinary amount of scar tissue she has from her condition, she must see a particular provider that can safely provide her with a colonoscopy. Unfortunately, this provider is not part of her insurer’s network. As a result, she pays \$2,500 each time she has a colonoscopy. As a result of this significant cost, she sometimes does not have her colonoscopy, despite being at high risk for colon cancer.

If a consumer is not able to access a preventive service at \$0 cost-sharing because the provider is an out-of-network provider or is a “tiered” provider, the beneficiary must be able to seek an exception. Some reasons why an exception should be granted in these cases include, but are not limited to: 1.) none of the in-network or tiered providers are accepting new patients, 2.) excessive wait times to see a provider 3.) the in-network or tiered provider is not accessible by public transportation and the consumer relies on public transportation, 4.) no in-network or tiered providers are able to meet the cultural or linguistic needs of the consumer, 5.) the patient has a long-term existing relationship with an out-of-network or non-tiered provider and changing providers would be harmful to the patient’s health, or 6.) the distance to the nearest in-network or tiered provider exceeds geographic access standards. The Medicaid Managed Care regulations may provide helpful guidance on geographic access standards.

The intent of the statute, whether the plan uses VBID, is to maximize access to preventive screenings to improve health, the quality of health care, and the cost-effectiveness of care delivered. Value-based insurance design should not be a mechanism that plans use to limit access to services or providers. An easily accessible exceptions and appeals process will ensure that consumers continue to have access to the services and providers they need.