PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

February 28, 2011

Steven Larsen
Director
Center for Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

Attention: HHS-OS-2010-002

Dear Mr. Larsen:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments in response to the Request for Information (RFI), "Request for Information Regarding Value-Based Insurance Design in Connection with Preventive Benefits," published in the Federal Register on December 28, 2010. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, and Medicare.

PCMA appreciates all the tasks that the Department of Health and Human Services must complete to implement the Patient Protection and Affordable Care Act (PPACA). We value opportunities to comment on the many aspects of regulations to implement the law, including comments regarding value-based insurance designs.

At the outset, PCMA believes it is critical for HHS to recognize that Value-Based Insurance Design (VBID) programs must remain flexible to respond to changes in clinical guidelines and marketplaces and new research findings in behavioral economics. Our responses to the specific questions in the RFI are below.

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?**

PCMA Response:

PCMA members employ a variety of design tools related to patient use of prescription drugs. Some PBMs waive or reduce copayments to drive behaviors, such as increased adherence. Some condition the waiver or reduction of copayment on participation in a disease/health management program. The goal is for increased medication adherence to lead to overall medical cost reductions. In addition, some PBMs offer programs that

incentivize patients to convert from certain higher-cost brand pharmaceuticals to lower-cost therapeutically equivalent generics. Most PBMs use data, sometimes in collaboration with health plans, to determine whether benefits designs are effective at increasing medication adherence, reducing emergency visits and hospitalizations, improving clinical outcomes and otherwise eliciting behaviors sought by the benefit designs. By definition, this is an iterative process, with the effects of program design studied and refined over time. Thus, it is critically important that benefit design for medical, pharmacy, behavioral health and other services be flexible to allow changes from year-to-year as health plans, employers, PBMs and other vendors of services understand better how plan designs work.

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)?**

PCMA Response:

With respect to pharmacy benefits, some programs target specific disease conditions while some apply more broadly. Examples of targeted diseases include diabetes, depression, hypertension, COPD and many others. Within the PBM, health plan and employer communities, companies are experimenting with benefit designs addressing a wide range of disease states as well as ways to incent enrollees to adhere to medications intended to prevent further development of disease.

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?**

PCMA Response:

Under VBID programs, some define "value" as the total health benefit gained as a result of a particular treatment. Others define value as an assessment of the clinical effect on a disease for a given cost.

Use of "high-value" services is encouraged through lower copays, contributions to fund-based plans, such as Health Savings Accounts, or by use of other rewards.

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?**

PCMA Response:

PCMA members determine incentive models with a focus toward evidence-based guidelines and clinical factors. Some of those factors include Food and Drug Administration reports, peer-reviewed medical information, manufacturer data and utilization management criteria. In addition, behavioral studies and evaluation of

populations using focus groups and surveys regarding best methods for incentivizing individuals may be used to determine incentive models.

In pharmacy benefits, because generic substitution is widely viewed to be a high-value benefit, PBMs typically tier their cost-sharing to incent use of generics, and studies address what level of cost-sharing will best both incent the use of generics and promote adherence to medications. In addition, since individuals taking medications to forestall further development of illness may become noncompliant within a few months of beginning drug therapy, PBMs have undertaken studies to determine what types of plan communications, interventions from health care professionals and benefit designs are most likely to lead to increased drug adherence.

These studies may demonstrate results that may be counterintuitive to some. For example, some studies have shown that individuals who receive medications for a zero co-pay believe that they are receiving a low-quality medication and that the programs are more successful if patients have to pay even a nominal amount. These studies have shown that patients show greater medication adherence if they pay a low co-pay than if they pay nothing. It is important that PBMs retain flexibility around incentive models to encourage the use of high-value services.

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

PCMA Response:

PCMA members review and update guidelines based on changing clinical parameters, new drugs coming onto the market, changes in drug-use trends, post-market surveillance and other feedback. While this evaluation may occur throughout the year, the updates most often occur on an annual basis. It generally takes multiple plan years for meaningful changes in medication adherence to be realized due to changes in plan design.

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?

PCMA Response:

A plan or issuer may decide not to adopt or continue a VBID program if it is overly focused on short-term costs. VBID programs are a longer-term investment. Increased adherence and utilization may lead to increased pharmacy costs in the short-term, but to long-term overall savings. In addition, some plans have found that similar savings may be achieved through other, less costly methods.

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

PCMA Response:

Appropriateness and the opportunity to drive quality are primary considerations. It also is important to adopt a VBID strategy in situations where the link between medication

adherence and outcomes is strong. Often, data is provided to plans and issuers that are considering VBID options and adherence rates are compared to industry peers.

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)?

PCMA Response:

Most PCMA members do not offer cost differentials based on population characteristics.

9. What would be the data requirements and other administrative costs associated with implementing VBIDs based on population characteristics across a wide range of preventive services?

PCMA Response:

Extensive configuration and development of computer systems usually are required for VBID systems and testing is required between plan sponsors and PBMs. Both medical and pharmacy claims are needed to do proper analysis and identify patients with targeted conditions. Data requirements may include:

- Demographics: age, gender, education, ethnicity, recruitment and retention levels
- Standard reports: cost drivers and drug adherence rates
- Disease management/case management/wellness experience/participation
- Health risk assessments and biometric data collected
- Pharmacy, medical and lab results
- Absenteeism data
- Disability data
- Total and condition-specific health care costs pre and post-VBID implementation

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?

PCMA Response:

Most plan sponsors that support VBID have programs that offer rewards for participation in a disease management program and there usually is little need for formulary exceptions. In addition, many plan sponsors choose to use so-called open formularies, which typically offer some coverage of most drugs, though potentially at a higher level of cost-sharing. Otherwise, step-therapy rules allow patients to receive a higher-cost agent

when the primary treatment has failed or is contraindicated. For some drugs, prior authorization requirements are established to ensure that the patient meets certain parameters with respect to test results and lab values, which demonstrate that the prescribed therapy is indeed appropriate for that patient. All health plans have appeals mechanisms, which apply to prescription drug benefits as well as medical benefits, so that enrollees may appeal a coverage determination with respect to a given medication or other prescribed treatment.

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

PCMA Response:

Formulary management and benefit design strategies that allow patients access to pharmacy services, which prevent and/or treat diseases based on evidence-based guidelines should be considered. Pharmacy benefits are offered through a large network of participating providers and medications identified on the preventive services list can be made available through network and benefit providers.

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

PCMA Response:

To some degree, VBID may simply be part of the standard health benefits offered to an enrollee. For example, tiering of drugs that provides generic drugs at a lower cost-sharing is essentially value-based insurance design and those benefits would be spelled out in summary plan materials, among other methods. To the extent that a VBID is part of a special program, consumers may be informed about programs through a variety of means, usually in their annual enrollment materials or by a separate letter. Typical sources include letters sent by the plan sponsor, PBM, health plan or disease management/wellness vendor. Other methods include member websites and information provided by telephone.

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

PCMA Response:

Because pharmacy benefits are adjudicated on a real-time basis, messages sent to pharmacists can be used to communicate preferred alternative therapies. With the anticipated increase in physician adoption of e-prescribing in 2012, real-time communication to physicians regarding preferred drugs and potential alternative therapies can be enhanced. Communications also may be sent to physicians regarding formulary and plan design recommendations and physicians may encourage enrollees to use appropriate medications.

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?

PCMA Response:

Preventive medications that are required to be covered under PHS Act section 2713 should be prescribed by a physician and subject to a PBM's quality and safety edits that currently are applied through real-time adjudication at the pharmacy.

We appreciate your consideration of our comments and look forward to continuing to work with the Departments of Treasury, Labor, and Health and Human Services to ensure successful implementation of PPACA.

Sincerely,

Michelle Galvanek
Vice President, Regulatory Affairs