



VIA Electronic Submission

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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

**RE: Request for Information Regarding Value-Based Insurance Design in
Connection with Preventive Care; HHS-OS-2010-002; 75 Federal Register 81544
(December 28, 2010)**

Dear Mr. Larsen:

CVS Caremark Corporation, on behalf of its subsidiaries and affiliated entities (“CVS Caremark”), appreciates the opportunity to provide information and comments on the use of value-based insurance design (VBID) in connection with preventive care services.

CVS Caremark is the leading provider of prescriptions in the nation, with over one billion prescriptions filled or managed annually. There are over 24,000 pharmacists and over 7,000 CVS/pharmacy retail stores within our company, and we are also a leading specialty and mail pharmacy services provider. CVS Caremark also operates approximately 500 MinuteClinic locations in 26 states and the District of Columbia that employ 1700 combined nurse practitioners and physicians’ assistants, providing convenient access to routine health care services. Our retail, mail and specialty pharmacies and MinuteClinics combined are leading providers of prescription drugs and health care services.

CVS Caremark appreciates the Department of Health and Human Services (HHS)’s recognition of the importance of VBID in promoting the use of appropriate preventive services in the preamble to the interim final rule (IFR) on preventive services.

While the term VBID emphasizes the value aspect of medical management techniques, it should be noted that the clinical components are equally important, and that the ultimate objective of such

techniques is not only to ensure the appropriate use of health services to keep coverage affordable, but also to improve health outcomes. The concept of VBID is not unlike the rationale behind accountable care organizations (ACOs), which the Affordable Care Act (ACA) seeks to promote in the Medicare Shared Savings Program to improve the quality of health care services and to lower health care costs.

In the ACO context, health care providers are encouraged to create integrated health care delivery systems that will test new reimbursement methods intended to create incentives for health care providers to enhance health care quality and lower costs. ACOs are required to meet certain quality performance standards and cost savings requirements established by HHS, and HHS seeks to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care. VBID seeks to achieve the same goals in non-governmental insurance programs by implementing innovative, clinically-based plan designs that not only incentivize more cost effective delivery channels and settings of care, but ensure that clinically appropriate care is delivered based on well-established, evidence-based clinical guidelines.

We believe HHS struck the right balance in allowing the use of reasonable medical management techniques in the coverage of preventive care services to ensure that preventive care is delivered in a manner that encourages the best clinical practices and the most effective use of health care resources. This is especially important where, as is the case with recommended preventive services, the services are provided without cost-sharing, which would otherwise help to promote cost effective and clinically appropriate choices.

We believe it is critical that HHS continue to allow reasonable medical management techniques to be used in the delivery of preventive care in order to keep coverage affordable and ensure that clinically appropriate care is provided. HHS should provide maximum flexibility to plans to determine which techniques to use and how to implement them, as long as safeguards are in place to ensure appropriate access to needed care.

Our responses to the specific questions raised in the *Federal Register* notice 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?

Plans use a variety of mechanisms to encourage patients to utilize health care services appropriately. These mechanisms depend on the type of care involved, plan design, clinical guidelines and many other factors. In pharmacy benefits, in addition to pharmacy networks, medical management techniques include prior authorization, step therapy, quantity limits, formulary management, and generic substitution. Most utilization management techniques have both cost and clinical elements, although the emphasis may differ from tool to tool.

For example, provider networks are generally designed to allow plans to negotiate better prices, which bring down the cost of care for both plans and their members. But networks also allow plans to require and enforce minimum quality standards, including provider qualifications, training and expertise. The use of networks allows plans to encourage practices that improve efficiency and medical safety, such as electronic prescribing, and appropriate drug utilization, such as through real time messaging to avoid adverse drug events and medical errors.

Other utilization management tools are more clinically-oriented, such as prior authorization (PA) requirements. PA generally involves confirming that certain clinical criteria based on established clinical guidelines are met before a particular medication is covered. It is typically used for a medication for which more cost effective or less powerful agents exist for treating a particular condition. Using PA, plans are better able to ensure that the most targeted and clinically appropriate drug is used in the circumstances. This is not only more cost effective but leads to better health outcomes in the long run with fewer complications and drug-resistance. Utilization management is also a mechanism to detect potential fraud and abuse and, in turn, lower the costs of health care generally.

The types of medical management techniques can change over time. New techniques are developed as new clinical information becomes available and clinical advances occur, such as in genetic medicine and other areas. In light of such changes, it is critical that plans not be limited to specific medical management tools or designs. Instead, plans should be allowed the flexibility to develop new tools and innovative designs to keep up with the advances in medicine. While there are many ways in which effectiveness can be defined, ultimately a tool is effective if it achieves its objective. Since different tools can have very different objectives, it is not necessarily meaningful to compare their effectiveness.

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)?

Some programs target specific disease conditions while some apply more broadly. Examples of targeted diseases include diabetes, depression, hypertension, COPD and many others with an emphasis on those conditions that contribute to significant total healthcare costs.

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 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 such as narrow and/or closed formularies, limited networks and utilization management programs.

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?

Extensive configuration and development of 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:

- Adherence Data
- 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

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 comorbidities 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?

All plans have in place appeals process to ensure that patients with special circumstances or risk factors can receive the care they need. Under health reform, there is now both an internal and an external appeals process that will allow patients for whom a particular provider setting or therapy is not effective or may be harmful, to have access to care in an appropriate setting or to a different therapy that is effective for them, even if it is more expensive or more powerful than most patients need. This is the purpose of the appeals process, which has also been streamlined under health reform so that it is easy to use, accommodates a culturally and linguistically diverse population, and results in prompt decisions in a matter of days or even hours where the situation warrants it. Lastly, most plan sponsors make an appeals process available to their members such that each patient has the opportunity to appeal to an independent medical review board their specific situation and receive a higher level decision around the justification for their desired service

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

Plans have more mechanisms than ever before to inform plan members about plan features, including any VBID or utilization management techniques. In addition to the traditional plan documents, such as Evidence of Coverage, provider directories, summary of benefits, and formulary, most if not all plans have web sites from which the most up-to-date information can be obtained, and customer call centers

with representatives trained to respond to all types of questions about the plan, and to provide information on key features of the plan, such as provider networks and formularies.

Under health reform, plan documents will become more uniform and will need to meet minimum standards of readability and disclosure so that plan members should be fully informed of how their plan works and what their options are. Many of these same mechanisms, such as web sites and call centers, are also available to providers so that they can take into account the plan features when developing a therapy plan for their patients. Many providers also have electronic prescribing capabilities which allow them to access plan formularies and even patients' drug histories so that they can consider these when deciding what to prescribe for their patients.

Consumers may be informed about programs through a variety of means, usually in their annual enrollment materials or by a separate letter or IVR phone call. Typically, these communications are sent by the plan sponsor, PBM, health plan or disease management/wellness vendor. Eventually, we would expect that these messages could be delivered in a face to face setting by an RPh at the retail counter or by a Nurse Practitioner at a retail clinic.

Conclusion

We appreciate the opportunity to comment on this request for information. If you have any questions, please contact me at (202) 772-3501.

Sincerely,

Russell C. Ring
Senior Vice President
Government Affairs