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Re: CMS-2334-P Medicaid Premiums and Cost Sharing

To Whom It May Concern:

The University of Michigan Center for Value-Based Insurance Design ([V-BID Center](#)) is pleased to offer comments on [NPRM CMS-2334-P](#). The V-BID Center leads in research, development and advocacy for innovative health benefit plans and payment reform initiatives. Established in 2005, the Center works to connect the research community and implementers, including employers, plan designers, consumer advocates and policymakers.

VALUE-BASED INSURANCE DESIGN

Value-Based Insurance Design (V-BID) refers to “clinically nuanced” insurance designs that vary consumer cost-sharing to distinguish between high-value and low-value health care services and providers. To efficiently reallocate medical spending and optimize population health, the basic tenets of clinical nuance must be considered. These tenets recognize that: 1) medical services differ in the benefit provided; and 2) the clinical benefit derived from a specific service depends on the patient using it. Thus, the basic V-BID premise calls for reducing financial barriers to evidence-based services and high-performing providers and imposing disincentives to discourage use of low value care. Payers, purchasers, taxpayers, and consumers can attain more health for every dollar spent by incorporating greater clinical nuance into benefit design.

The available literature indicates that incentive-based V-BID programs (“carrots”) can improve quality of care and reduce undesirable acute care utilization, such as emergency room visits and hospitalizations.¹ When targeted correctly, these incentive-only programs can be cost neutral in regard to direct medical expenditures over the medium term. Additionally, a V-BID approach to low-value services avoids indiscriminate “across-the-board” increases in patient cost-sharing which, in turn, can reduce the utilization of high-value services.² V-BID approaches use clinically targeted increases in cost-sharing to discourage patients’ use of specific low-value services such as those identified through the Choosing Wisely project.³ **V-BID programs that include both carrots and sticks may be particularly desirable for states facing budget shortfalls.**

¹ University of Michigan Center for Value-Based Insurance Design. V-BID Center Brief. The Evidence for V-BID: Validating an Intuitive Concept. November 2012. Available at:

<http://www.sph.umich.edu/vbidcenter/publications/pdfs/VBID%20brief%20Evidence%20Nov2012.pdf>

² Fendrick AM, Smith DG, Chernew ME. Applying Value-Based Insurance Design To Low-Value Health Services. Health Affairs. 2010;29(11):2017-21.

³ <http://www.abimfoundation.org/Initiatives/Choosing-Wisely.aspx>

OVERVIEW

State Medicaid programs cover some of the nation's most vulnerable citizens and encompass a large portion of state budgets. With the implementation of Medicaid program expansion in 2014 as a result of the Patient Protection and Affordable Care Act, the number of eligible enrollees will significantly increase, as will direct medical expenditures made by the federal government and the states.

CMS proposed rules establishing higher cost-sharing for certain outpatient services, non-preferred drugs, and non-emergent use of the emergency department. This added flexibility in enrollee cost-sharing is aimed at the important goals of reducing unnecessary and costly service utilization; enhancing personal responsibility; simplifying administrative procedures; and promoting coordination in eligibility, verification, and enrollment systems across multiple health coverage programs. **The potential role for V-BID principles—applying clinical nuance that limits the use of low value services and providers—in the implementation of these innovative cost-sharing strategies is significant. If V-BID principles are used to set enrollee cost-sharing levels, Medicaid programs can reduce costs, remove waste, and mitigate the legitimate concern that non-nuanced cost-sharing may result in enrollees forgoing clinically important care that may lead to adverse health events.** We appreciate the opportunity to comment on these critical issues.

§447.52 MEDICAID OUTPATIENT SERVICES COST-SHARING

As stated in the NPRM, the existing guidelines around permissible cost-sharing for outpatient services in Medicaid can be “confusing and burdensome for states, providers and beneficiaries.” **The V-BID Center supports the proposed rule’s update to the maximum levels of permissible cost-sharing for outpatient services.** The proposed new schedule for permissible cost-sharing for outpatient services is as follows:

- \$4 maximum allowable charge, for enrollees with family incomes under 100 percent of FPL;
- 10 percent of Medicaid’s cost for the service, for enrollees with family incomes between 101 and 150 percent of FPL; and
- 20 percent of Medicaid’s cost for the service, for enrollees with family incomes greater than 150 percent of FPL.

Regardless of these proposed guidelines, states may not impose cost-sharing of any sort for outpatient services delivered to certain groups, including children living in families under 100 percent of FPL and pregnant women. On the whole, the new regulations will represent a more consistent policy.

I. Flexibility in Imposing Differential Cost-Sharing for Outpatient Services of Different Value

We support the notion that outpatient services have inherently different clinical values and note that under the proposed regulation, Medicaid programs are free to vary cost-sharing on select outpatient services. This means, for instance, that states may choose to impose the maximum allowable cost-sharing for use of low-value services—such as those identified in the Choosing Wisely initiative³ or the U.S. Preventive Services Task Force (USPTF) Grade D recommendations. These targeted increases on low-value services may be implemented while exempting high-value services—such as those quality indicators identified by the National Quality Forum and the National Committee for Quality Assurance or those services rated A or B by the USPSTF from enrollee cost-sharing. **We encourage CMS to draw attention to this important concept of clinical nuance by adding an additional sentence to §447.52(a) stating: “States may identify services for enrollee cost-sharing on the basis of clinical value.”**

II. Flexibility in Imposing Differential Cost-Sharing for Use of Different Providers or Care Settings

Since the value of a clinical service may depend on the specific provider or the locus of care delivery, we encourage CMS to clarify whether states can vary cost-sharing for a particular outpatient service in accordance with where the service is provided and by whom. This flexibility might be useful when states have identified certain high-performing health care providers or care settings that consistently deliver superior quality. For example, a state might wish to impose a \$4 copayment for all office visits, except those office visits that take place at a recognized patient-centered medical home (PCMH). Similarly, a state may wish to impose different levels of cost-sharing when a given service is delivered in a high quality, lower-cost ambulatory surgical center or a more expensive in-hospital procedure unit. Accordingly, we recommend adding language under §447.52(a) stating: **“States may waive or reduce cost-sharing for outpatient services delivered by designated high-value providers or in high-value care settings, even if those services may otherwise be subject to cost-sharing.”**

III. Flexibility in Imposing Differential Cost-Sharing Across Enrollees

Since a critical aspect of clinical nuance is that the value of a medical service depends on the person receiving it, we applaud the proposed rule’s flexibility for state Medicaid agencies to target specific groups of enrollees in families earning more than 100 percent of FPL. In doing so, CMS has recognized that there are compelling reasons for Medicaid programs to impose different levels of cost-sharing on different groups of enrollees for certain medical services. **The flexibility to target enrollee cost-sharing based on clinical information (e.g., diagnosis, clinical risk factors, etc.) is a crucial element to the safe and efficient allocation of states’ Medicaid expenditures.** Under such a scenario, a state may choose to exempt certain enrollees from cost-sharing for a specific service on the basis of a specific clinical indicator, while imposing cost-sharing on other enrollees for which the same service is not clinically indicated. Under such a clinically nuanced approach, states can recognize that many outpatient services are of particularly high-value for beneficiaries with conditions such as diabetes, hypertension, asthma, and mental illness, while of low-value to others. (For example, annual retinal eye examinations are recommended in evidence-based guidelines for enrollees with diabetes, but not recommended for those without the diagnosis.) Without easy access to high-value secondary preventive services, previously diagnosed individuals may be at greater risk for poor health outcomes and avoidable, expensive, acute-care utilization. Conversely, keeping cost-sharing low for these services for all enrollees, regardless of clinical indicators, can result in overuse or misuse of services leading to wasteful spending and potential for harm.

We encourage CMS to define states’ flexibility on the matter of varying cost-sharing by clinical indicators more explicitly in the final rule. **To this end, we suggest additional language for §447.52(c) stating: “Cost sharing for specific services delivered to non-exempt enrollees may vary on the presence or absence of specific medical condition(s) or risk-factor(s), and the expected clinical value of specific services for those enrollees.”**

§447. 53 COST-SHARING FOR DRUGS

The V-BID Center strongly supports CMS’s proposal in §447.53 to provide states with the additional flexibility for differential cost-sharing between preferred and non-preferred drugs. The proposed schedule for cost-sharing for preferred and non-preferred drugs is as follows:

- \$4 maximum allowable charge for preferred and non-preferred drugs for individuals with family incomes below 150% FPL;
- \$8 maximum allowable charge for non-preferred drugs for individuals with family incomes above 150% FPL; and
- 20% of the cost the agency pays for non-preferred drugs for individuals with incomes above 150% FPL.

Given the considerable evidence examining the impact on various levels of enrollee cost-sharing on drug adherence, we believe it is extremely important to allow states to differentiate enrollee cost-sharing for prescription drugs based on their clinical value. This flexibility will allow states to develop innovative cost-sharing structures that will encourage the use of high-value therapies and discourage harmful and low-value treatments. Thus, **the V-BID Center strongly recommends that the definition of preferred drugs not be restricted to low-cost or exclusively generic agents, and should encourage the inclusion of high-value brand agents, especially when a generic equivalent is not available.** Under this clinically-motivated definition, the V-BID Center fully supports the proposal allowing states to vary cost-sharing between preferred and non-preferred prescription drugs.

The proposed rule retains the state's ability to differentiate preferred and non-preferred drugs within their programs through Preferred Drug Lists (PDLs). We support the flexibility for states to choose preferred drugs "in whatever manner they consider most effective," as stated in the proposed rule. However, we strongly suggest that preferred drugs are chosen based on their clinical value and not solely on their acquisition cost.

A substantial body of published evidence concludes that increases in patient cost-sharing for prescription drugs results in reduced use of both high-value and low-value drugs.¹ Conversely, lowering financial barriers through altered cost-sharing structures for high-value drug classes increases adherence, slows progression of a chronic disease, and in some instances may lower overall costs.¹ These findings regarding consumer responses to changes in drug cost-sharing are critically important, since research demonstrates that higher out-of-pocket costs for drugs have a greater negative effect on adherence in low-income populations.⁴

Thus, we believe that states should evaluate drugs based on clinical value when considering modifying the status of different classes of drugs for their PDLs. **As such, the V-BID Center encourages CMS to add language to 446.53 stating, "Preferred and non-preferred drugs may be chosen based on clinical value, not solely on the basis of acquisition price."**

We believe that the addition of this provision will encourage states to leverage research on the impact of copayment levels on medication adherence to promote the use of drug classes with a proven benefit and potentially steer beneficiaries away from harmful, low-value treatments. This approach will likely result in better health outcomes and lower aggregate Medicaid expenditures. These clinically-driven concepts will be particularly valuable to states when they are considering changes to a given class of drugs' status in the PDL. **We encourage CMS to promote the concept of clinical value when discussing prescription drug cost-sharing arrangements and PDLs with state Medicaid programs in the future.**

§447.54 NON-EMERGENT USE OF THE EMERGENCY DEPARTMENT

Section §447.54 of the proposed rule gives states the option to impose cost-sharing for non-emergency services provided to Medicaid enrollees in the emergency department (ED). **Due to the lack of a consistent and applicable definition of a non-emergent ED visit and an insufficient number of adequate provider networks, we believe that it is imprudent for the Centers to widely implement substantial levels of cost-sharing for non-emergency services for Medicaid enrollees.** Until it is certain that increases in ED cost-sharing can be accurately applied only for truly non-emergent scenarios, and that access to appropriate care is confirmed for all enrollees in the non-emergent cases, concerns will remain that the perception of an increased copayment for ED visits may cause Medicaid enrollees to delay or forgo necessary care which may lead to adverse health outcomes and increased costs in the long run.

⁴ Chernew M, Gibson TB, Yu-Issenberg K, Sokol MC, Rosen AB, Fendrick AM. Effects of increased patient cost sharing on socioeconomic disparities in health care. J Gen Intern Med. 2008;23(8):1131-6.

I. Definition for Non-emergent Use of Emergency Department

As stated in §447.51, non-emergency services are defined as “any care or services that are not considered emergency services as defined in this section and any services furnished in a hospital emergency department that do not constitute an appropriate medical screening examination or stabilizing examination and treatment.” In its current form, this vague definition makes it unlikely that states can successfully and consistently apply such a cost-sharing rule. Until a widely accepted, practical definition of a “non-emergent ED visit” is agreed upon, we do not recommend widespread implementation of cost-sharing increases for non-emergency use of the ED among Medicaid enrollees.

II. The Need for Adequate Provider Networks

We would like to express our support for the definition of an alternative non-emergency services provider, as specified in §447.51. However, prior to establishing increases in enrollee cost-sharing for non-emergency use of the ED, adequate provider networks must be in place to care for all non-urgent cases. This would ensure that Medicaid enrollees would receive clinically recommended services in the appropriate care setting. This would require an assessment of care delivery infrastructure, since many states’ Medicaid programs lack adequate provider networks that meet the “accessible alternative provider” criteria noted in the proposed rule. **As such, we recommend that CMS should do more to encourage states to establish networks that include these alternative non-emergency services providers, and that states should have the flexibility to establish definitions of alternative providers based on state law.**

Published research suggests that requiring cost-sharing for non-emergent ED visits did not decrease ED utilization.⁵ For this reason, and the ongoing concern that the perception of increased cost sharing may deter Medicaid enrollees from seeking necessary emergency care, we recommend that two criteria be met before increased levels of cost sharing for non-emergent ED visits are implemented. First, there must be a widely-accepted clinical definition for non-emergent use of the ED that can be applied by providers and payers and easily communicated to enrollees—paying particular attention to the issues of language comprehension and medical literacy. Second, adequate provider networks must be in place to meet the needs of the “accessible alternative provider” criteria noted in the proposed rule.

III. Reasonable Limits to Cost-Sharing for Non-Emergent Use of Emergency Department

It is critical to examine the clinical effects of imposing cost-sharing on a resource-restricted group. Should the Centers move forward with §447.54 in its current form, we are concerned with part 5 of §447.54 that states, “For individuals with family income above 150 percent of the FPL there is no limit on the cost-sharing that may be imposed for non-emergency use of the ED.” Given the vague definition of non-emergency use noted above and the inherent difficulty for a lay-person beneficiary to accurately determine non-emergent use of the ED, the proposed rule should include a reasonable limit to cost sharing for non-emergency use of the ED for individuals with family income above 150% FPL.

CONCLUSION

We strongly support the proposed rule that would provide flexibility to Medicaid plans to vary enrollee cost-sharing in a clinically nuanced way that encourages beneficiaries to use high-value interventions and discourages the use of low-value services that do not improve health.

⁵ Mortensen, K. Copayments Did Not Reduce Medicaid Enrollees’ Nonemergency Use Of Emergency Departments. Health Affairs. 2010;29(9):1643-1650.

To the extent permitted by statute, we encourage CMS to expand this flexibility to reduce or waive cost-sharing to include individuals in families earning less than 100 percent of FPL, who would otherwise be subject to cost-sharing. Additionally, we encourage CMS to examine how the use of clinical nuance in enrollee cost-sharing may be applied to Medicare Advantage and Part D plans. There are approximately 9 million people who are considered to be Medicare-Medicaid dual-eligible and thus receive their prescription drug coverage through the Medicare Prescription Drug Program. These beneficiaries currently do not have access to the same types of value-driven plans, which can lead to better healthcare outcomes and lower expenditures.

The ultimate test of health reform will be whether it expands coverage in a way that promotes access to care, improves health, and addresses rapidly rising costs. Instead of focusing exclusively on spending levels, a clinically-motivated, value-driven strategy that encourages the use of clinically-effective care and discourages the use of low value services can lower health care cost trends while improving total health outcomes. Our multidisciplinary team of University of Michigan researchers introduced the concept of Value-Based Insurance Design over a decade ago. We have worked with hundreds of health care stakeholders to promote its implementation and evaluation, and believe strongly that this approach can help Medicaid plans achieve more health for the money spent. We are delighted to provide input to this process, and look forward to an ongoing interaction as the Departments develop further guidance advancing this important innovation in benefit design for Medicaid enrollees.

Please contact us if you require any additional information.

Sincerely,



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