


Acknowledgements

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Executive Summary

Value-based insurance design (VBID) has emerged as a potentially viable approach to promote healthcare value. VBID abandons the traditional approach of uniformly applying cost sharing to health services regardless of their effect on a patient's health. Instead, VBID tailors cost sharing to the value that the service provides the beneficiary in terms of health gained per dollar spent. The more clinically beneficial the service is to a patient, the lower that individual's cost sharing for the service.

Given the growing need to increase the value of care delivered in the Medicare program and the existing evidence suggesting that VBID can generate cost savings and improve health outcomes, there are clear opportunities to explore how to implement VBID within the Medicare program. This analysis presents options for advancing a VBID approach within Medicare's prescription drug benefit (Part D), and specifically focuses on differential cost sharing for chronically ill beneficiaries and high-value medications that target chronic conditions.

Our analysis of the current structure of the Medicare Part D program identified five options for implementing VBID in the Part D program:

- Option 1:** Reduce cost sharing for specific drugs or drug classes
- Option 2:** Exempt specific drugs or drug classes from 100 percent cost sharing in the coverage gap
- Option 3:** Reduce cost sharing for enrollees with chronic conditions
- Option 4:** Reduce cost sharing for enrollees participating in medication therapy management programs (MTMPs)
- Option 5:** Reduce cost sharing for chronic condition special needs plans (CC-SNPs)

We evaluated the feasibility of each of these policy options based on four criteria: 1) potential size of the Medicare Part D population affected (using diabetes to estimate the relative size of the affected population for options that target specific chronic conditions, and hypoglycemics and insulin for options that target particular drugs); 2) the Centers for Medicare & Medicaid Services' (CMS) authority to change policy within existing statute and regulation; 3) requirements for implementation; and 4) political support.

Based on our evaluation, it appears that several options could be successful vehicles for VBID in Medicare Part D. In particular, **Option 1** targeting specific drugs or drug classes is an option that CMS can implement under current law, and has the potential to affect approximately 6 million Part D enrollees with diabetes. In fact, at least one Part D plan, UnitedHealthcare's Senior Dimensions, began exercising this option in 2008. **Option 2** is also presently available to plans and, while affecting fewer beneficiaries, it targets those patients with high annual drug spending who may benefit most from this type of intervention. However, in 2009 only three drug-only prescription drug plans (PDPs) offer gap coverage for any brand-name medications. As more evidence of the benefits of VBID becomes available, policymakers may wish to pursue legislative changes that would create new incentives to encourage more Part D plans to adopt this type of benefit.

Option 5 is also feasible in the current policy environment. However, targeting VBID to enrollees in CC-SNPs will have a limited impact on the Medicare population – currently about 268,000 beneficiaries, only 1 percent of Part D enrollment. Due to the small scale of this option's

impact, **Option 5** may be an ideal first step in implementing VBID in the Medicare Part D program. CMS and policymakers could encourage CC-SNPs to incorporate VBID into their benefit designs and to collect data on adherence and outcomes for their enrollees. As CC-SNPs gather evidence on the value of VBID in this population, policymakers could consider additional methods for incorporating VBID into the Medicare Part D program more broadly.

While not the highest-ranked alternative, **Option 4** presents an interesting opportunity to demonstrate the value of VBID, despite potential legislative challenges in authorizing such an option. Since this option would require differences in benefit design for beneficiaries within the same plan, regulatory or legislative changes may be necessary to exempt VBID from existing Part D requirements that plans may not discriminate against certain groups of beneficiaries and that all enrollees in a plan must be subject to a uniform benefit design, including cost sharing. While MTMPs presently attract only a small number of Part D enrollees—8 percent of beneficiaries in 2007—linking VBID to MTMP participation could boost MTMP enrollment. The move could also positively reinforce MTMP efforts to improve beneficiaries' medication adherence by lowering or removing financial barriers for those services recommended by the program. Policymakers may be interested in examining this option further to determine the impact on health outcomes and overall costs or savings.

Finally, while **Option 3** has the potential to reach a large number of Part D beneficiaries and could be a cost-effective approach to implementing VBID, the potential legislative and regulatory changes required appear to be barriers to its implementation, making this a less attractive option.

Over the course of the past two years, a diverse group of stakeholders across the healthcare enterprise has expressed support for VBID. Because the percentage of health services with unequivocal clinical evidence to support their use under VBID programs is small in relation to aggregate medical expenditures, even groups that might typically oppose such efforts as "paternalistic" have been receptive to this idea.

Overall, political support for VBID appears to be strong, bipartisan, bicameral, and growing. The policy changes identified in this paper provide a roadmap for several scenarios that will advance VBID principles in efforts to improve health and contain costs.

In brief, this paper illustrates that Congress, CMS, and others have several viable options for the Medicare program to implement VBID in Part D. Each of these options have their own strengths and weaknesses based on how many Medicare beneficiaries may benefit and how easily the particular VBID approach could be implemented by Congress, CMS, and health plans. Each of these factors, moreover, is dynamic and our evaluation of these options is sensitive to changes in the Medicare Part D market.

As the Obama Administration and members of Congress explore health reform options, it is important that they not only examine options to increase coverage for the uninsured, but also options to improve quality and contain costs. VBID simultaneously addresses the objectives of cost containment and quality improvement in the delivery of care by promoting "fiscally responsible, clinically sensitive" cost sharing in order to mitigate the well-documented adverse clinical outcomes associated with the current, one-size-fits-all medical system. Medicare is an ideal place to implement VBID because beneficiaries are at a much higher risk of adverse events due to non-adherence than younger patient populations and ensuring access to necessary care is a fundamental tenet of the Medicare program. VBID is a vital tool that has the potential to transform Medicare into a more prudent purchaser of healthcare services that meet patient needs.

VBID is not a mechanism that will solve our healthcare crisis. Technological advances will continue to generate upward pressure on costs and increasingly strain the ability of individuals and their employers to afford such coverage. That said, compared to the status quo of escalating costs and suboptimal quality of care, the implementation of VBID principles would encourage the use of high-value care and ultimately produce better health at any level of healthcare expenditure.

Introduction

The United States is on a quest for better value in the healthcare system. Research demonstrating wide variation in health spending and the quality of care patients receive has fueled purchasers of healthcare to seek reform options that generate a more favorable return on investment (i.e., more health benefit) for their healthcare dollar.¹ In fact, many policymakers view health reform efforts to expand insurance coverage to America's under- or uninsured without promoting a more value-driven healthcare system as shortsighted and unsustainable.

Traditionally, when faced with rising healthcare costs, payers have turned to raising patients' share of costs for healthcare services. However, a growing body of evidence suggests that doing so reduces patient utilization of both unnecessary and necessary healthcare services, especially for patients with chronic conditions who already face high out-of-pocket costs.² Studies have linked increases in cost sharing with lower use of essential clinical services, such as prescription drug use and valuable preventive screening.³ As a result, adverse health outcomes may require costly emergency room visits and hospitalizations.⁴ Consequently, employers, patients, and policymakers seek solutions to reduce the growth in health spending without sacrificing patient health.

The search for value and the need to identify cost containment options that do not result in poorer health outcomes for patients is most acute in the Medicare program. An estimated 83 percent of Medicare beneficiaries have at least one of the following chronic conditions: diabetes, arthritis, hypertension, asthma, or heart disease.⁵ Additionally, the 23 percent of beneficiaries with 5 or more chronic conditions account for 68 percent of the program's spending.⁶

Value-based insurance design (VBID) has emerged as a potentially viable approach to promote healthcare value. VBID abandons the traditional approach of uniformly applying cost sharing to health services regardless of their effect on a patient's health. Instead, VBID tailors cost sharing to the value that the service provides the patient in terms of health gained per dollar spent.⁷ The more clinically beneficial the service is to a patient, the lower that individual's cost sharing for the service.

This innovative benefit design aligns incentives by offering advantages to both payers and patients. By reducing financial barriers to essential clinical services, patients are more likely to adhere to their prescribed treatment regimens and appropriately manage their health. In return, payers may reduce healthcare costs in the long run by helping enrollees prevent costly health emergencies.⁸ To date, the majority of VBID efforts that have generated positive results have focused on reducing cost sharing for prescription drugs used to treat chronic conditions, mainly diabetes and

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- 1 Fisher E, et al. "Regional Variations in Health Care Intensity and Physician Perceptions of Quality of Care." *Ann Intern Med* 144, no.9 (2006): 641-649.
 - 2 Braithwaite, et al. "Linking Cost Sharing to Value: An Unrivaled Yet Unrealized Public Health Opportunity." *Ann Intern Med* 146 (2007): 602-605.
 - 3 Newhouse, Joseph, Insurance Experiment Group. *Free for All? Lessons from the RAND Health Insurance Experiment*. Cambridge, MA: Harvard University Press; 1993.
 - 4 Thomas, CP. "How Prescription Drug Use Affects Health Care Utilization and Spending by Older Americans: A Review of the Literature." AARP Public Policy Institute (April 2008).
 - 5 Neumann P, et al. "Medicare Prescription Drug Benefit Progress Report: Findings from a 2006 National Survey of Seniors." *Health Affairs Web Exclusive* 26.5 (August 21, 2007): w630-w643.
 - 6 Anderson, Gerard. "Medicare and Chronic Conditions." *NEJM* 353, no.3 (2005):305-309.
 - 7 Chernew ME, et al. "Value-Based Insurance Design: By Abandoning the Archaic Principle that All Services Must Cost the Same for All Patients, We Can Move to a High-Value Health System." *Health Affairs* 26, no.2 (2007): w195-w203.
 - 8 Fendrick AM, et al. "Value-Based Insurance Design: Fiscally Responsible, Clinically Sensitive Approach to Making The Most Of Health Dollars." *AJMC* 13. (June 2007): 325-327.

VBID in Practice

In practice, there are two general approaches to VBID. The first approach targets clinically valuable treatments, tests, or procedures, such as chronic condition maintenance medications or preventive mammography, for reduced cost sharing for all enrollees. The second VBID approach targets patients with specific clinical diagnoses, such as diabetes, and lowers cost sharing for the high-value services necessary to manage these conditions, such as insulin or eye care.⁹ Although the application of both approaches to VBID is possible for any medical service, to date most efforts have focused on reducing cost sharing for prescription drugs used to treat chronic conditions, mainly diabetes and hypertension, with the intent of improving adherence and disease management.

Employers, including Pitney Bowes, Marriott, and the University of Michigan, have championed VBID initiatives that reduce cost sharing for chronic condition medications to encourage high-risk patients to manage their disease better.^{10,11,12,13} Pitney Bowes, for example, reduced cost sharing for drugs commonly prescribed for diabetes, asthma, and hypertension and reported favorable results. In 2009, UnitedHealthcare launched a VBID-type health plan with copayment relief specifically for beneficiaries with diabetes mellitus. For employees with diabetes, the reductions in cost sharing increased medication adherence by 20 percent and decreased diabetes-related medical costs by 6 percent.¹⁴ Given the positive outcomes VBID has generated for these employers and others, many advocates believe the broader use of VBID would benefit the healthcare system.

hypertension. The reductions in out-of-pocket payments for these patients have led to improved medication adherence, better clinical outcomes, and decreased healthcare costs through averted hospitalizations and emergency room visits.^{15, 16} The Appendix provides a summary of recent VBID studies on differential cost sharing for drugs used to treat certain chronic conditions.

Given the growing need to increase the value of care delivered in the Medicare program and the existing evidence suggesting that VBID can reduce healthcare costs and improve health outcomes, there are clear opportunities to implement VBID within the Medicare program. This analysis will present options for advancing a VBID approach within Medicare's prescription drug benefit (Part D), and specifically focuses on differential cost sharing for chronically ill beneficiaries and high-value medications that target chronic conditions. As a follow-up to this study, Avalere Health and the University of Michigan VBID Center are collaborating on a second paper that will examine the impact of implementing a VBID approach in the Medicare Part D program.

Although this analysis focuses on the application of VBID to chronic condition medications covered under Medicare Part D, it is important to recognize that VBID has a much broader application

9 Chernew, *Health Affairs*.

10 Cranor C.W., et al. "The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program," *JAMA* 43, no.2 (2003): 173-184.

11 Berger, J. "Economic and Clinical Impact of Innovative Pharmacy Benefit Designs in the Management of Diabetes Pharmacotherapy," *AJMC* 13, no.2 (2007): S55-58.

12 Sokol MC, et al. "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost." *Med Care* 43, no.6 (2005): 521-530.

13 Results from M-Healthy: Focus on Diabetes two-year pilot program (unpublished study data reported in *Drug Benefit News*) December 12, 2008.

14 Berger, *AJMC*.

15 Sokol, *Med Care*.

16 Berger, *AJMC*.

than differential cost sharing. The concept of VBID is part of the larger paradigm shift to value-based purchasing, which seeks to align incentives with evidence-based healthcare delivery.

The potential promise of VBID in the Medicare Part D program is significant. On average, this population takes at least five prescription drugs a day.¹⁷ However, despite the central role that prescription drugs play in managing chronic conditions, lack of adherence to medication regimens is a serious problem among the Medicare population.¹⁸ For example, a national survey of Medicare beneficiaries found that nearly 20 percent of Part D enrollees either did not fill a prescription or delayed filling a prescription because of cost.¹⁹ Poorly controlled chronic conditions are also associated with high medical costs. Researchers have found that improving medication adherence can cut medical costs in half for patients with diabetes and high cholesterol.²⁰ Studies that have examined the impact of lowering or eliminating cost sharing for outpatient drugs for Medicare beneficiaries with chronic conditions report cost savings and improved health outcomes.²¹ For example, one study found that providing full coverage of ACE inhibitors for Medicare beneficiaries with diabetes could generate savings of \$1,606 per beneficiary per year.²²

Political support for broader application of VBID is gaining momentum. At the federal level, Congress and support agencies such as the Medicare Payment Advisory Commission (MedPAC) are exploring how to incorporate VBID into federal programs. Sen. Max Baucus (D-MT) supported the concept in his "Call to Action" white paper on healthcare reform,²³ and Sen. Debbie Stabenow (D-MI) and Rep. John Dingell (D-MI) hosted a February 2009 congressional briefing on VBID. In 2007, MedPAC discussed implementing VBID within Medicare.²⁴ Most recently, a bipartisan group of U.S. Senators is drafting legislation to advance VBID in the Department of Veterans Affairs (VA). This population is particularly well-suited to VBID because the VA's use of an electronic health records system provides the structure necessary for efficient implementation; the impact of reducing copayments can be easily tracked and linked to a patient's medical diagnosis. State governments are also beginning to incorporate VBID principles into their benefit designs as a way to promote healthy behavior. For example, Michigan is working to integrate VBID principles into its Medicaid program by waiving copayments on certain maintenance drugs for chronic diseases.²⁵

17 Wilson I, et al. "Physician-Patient Communication About Prescription Medication Nonadherence: A 50-State Study of America's Seniors." *J of Gen Intern Med* 22, no.1 (2007): 6-12.

18 Thomas, *AARP Public Policy Institute*.

19 Neumann, *Health Affairs*.

20 Sokol, *Med Care* p.525.

21 Thomas, *AARP Public Policy Institute*.

22 Rosen AB, et al. "Cost-effectiveness of Full Medicare Coverage of Angiotensin-Converting Enzyme Inhibitors for Beneficiaries with Diabetes." *Ann Intern Med* 143 (2005):89-99.

23 Baucus, Sen. Max. "Call to Action: Health Reform 2009." (November 12, 2008) <http://finance.senate.gov/healthreform2009/home.html> (accessed January 5, 2009).

24 MedPAC Meeting. October 3, 2007. <http://www.medpac.gov/transcripts/1003-04medpac.final.pdf> (accessed January 5, 2009).

25 "Public Programs are Using Incentives to Promote Healthy Behavior." The Commonwealth Fund. (October 11, 2007). http://www.commonwealthfund.org/innovations/innovations_show.htm?doc_id=676105

Methodology

Avalere Health and the University of Michigan VBID Center conducted this analysis from December 2008 through February 2009. We examined published studies on VBID, policy documents, and other publicly available materials to inform the development of options and the analysis. We then identified policy options for incorporating VBID into the Medicare Part D benefit based on examples of employer-sponsored VBID programs, policy options considered for implementation in the Medicare Part D program, and our collective understanding of VBID and Medicare policies.

For each policy option identified, we assessed the size of the Medicare population affected; determined the Centers for Medicare & Medicaid Services' (CMS) authority to authorize the option within existing statutes and regulations, and whether legislative or regulatory action is required; requirements for implementation; and political support. We then ranked each option's impact and feasibility according to the scale described in Table 1.

TABLE 1. Rating Scale for Options Analysis

	● Greatest Potential Most Feasible	◐ Moderate Potential Moderate Feasibility	○ Lowest Potential Least Feasible
Potential to Improve Medicare			
Size of Medicare Population Affected	Largest population relative to other options considered	Mid-size population relative to other options considered	Smallest population relative to other options considered
Feasibility			
CMS Authority to Change Policy	May be authorized under current law and regulation	May require change in CMS regulations or sub-regulatory guidance	May require legislative change to authorize option
Ability to Implement Policy	Requires minor changes to CMS and plan operations	Requires moderate changes to CMS and plan operations	Requires major changes to CMS and plan operations
Political Support	High likelihood of political support; significant advantages to policy change	Moderate likelihood of political support; some advantages and obstacles to policy change	Low likelihood of political support; significant obstacles to policy change

However, it is important to note that this analysis does not seek to assess the value of medications or distinguish between low- and high-value treatments. These are important considerations when implementing VBID, but beyond the scope of this paper. Rather, our goal is to identify potential VBID policy options within the Medicare program; evaluate each option; and determine the most feasible options with the greatest potential for impact.

We describe each of our options as targeting chronic conditions, but do not attempt to define which conditions or classes of drugs should be the focus of a VBID approach in Medicare. However, we use diabetes throughout the paper as an example of how an option's implementation might look. We selected diabetes due to its appearance in the VBID literature as one of the most commonly studied conditions, as well as the potential for payers and beneficiaries to see short-term positive outcomes and possible savings for VBID targeting diabetes compared to other conditions. Diabetes is one of the most common chronic conditions among Medicare beneficiaries and one

of the most costly, accounting for \$11,800 in annual program costs for the average beneficiary with diabetes.²⁶ Additionally, policymakers have highlighted diabetes as a priority condition for the Medicare program through recent changes adding coverage of diabetes screening tests and specifying diabetes as one of a limited number of chronic conditions special needs plans (SNPs) may target.^{27,28} Do not interpret our use of diabetes throughout this paper as singling out the disease as the only condition or class of drugs that VBID could target.

At the same time, because we use diabetes as an example in a primarily qualitative analysis, we have not defined the specific medications that plans could seek out in a VBID approach designed around diabetes. For example, a plan implementing VBID for enrollees with diabetes could take a narrow approach by reducing cost sharing for oral hypoglycemic medications and insulin only, while a broader approach could include cardiac medications, antidepressants, or other medications often utilized by diabetics. For the purposes of our analysis, we have used the narrower definition, but Part D plans or policymakers interested in defining VBID must decide how narrowly or broadly to approach the issue.

Finally, while this paper focuses on the VBID model of reduced cost sharing, there are many other approaches possible to improve beneficiaries' adherence and health outcomes in Part D. Pairing programs that offer counseling with pharmacists or other chronic disease management initiatives with VBID's lower cost sharing could have an even greater impact on beneficiary health.

26 Tan, Ronnie. "Characteristics of Medicare Beneficiaries with Chronic Conditions." Presentation at 2007 Academy Health, June 4, 2007. <http://www.academyhealth.org/2007/monday/asial/tanr.pdf>

27 CMS, "Diabetes Screening: Overview." <http://www.cms.hhs.gov/DiabetesScreening/>

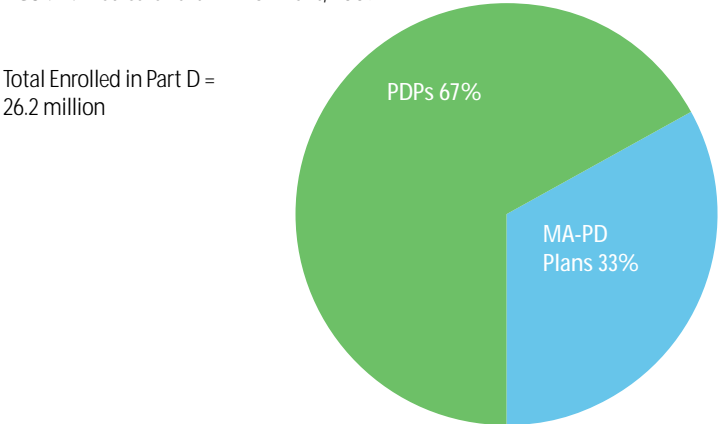
28 CMS, Special Needs Plan Chronic Condition Panel, Final Report. November 12, 2008. <http://www.cms.hhs.gov/specialneedsplans/>

Exploring VBID in the Medicare Part D Program

Medicare’s prescription drug benefit provides coverage of most outpatient drugs for Medicare beneficiaries. Unlike other parts of Medicare, Part D drug coverage is only available through private insurance plans. Everyone covered by Medicare is entitled to receive prescription drug coverage, although enrollment is voluntary.

Beneficiaries who choose to obtain Part D coverage have two options—enroll in a standalone prescription drug plan (PDP) that offers drug-only coverage or select a Medicare Advantage prescription drug plan (MA-PD plan), providing coverage of both medical and drug benefits. As of January 2009, more beneficiaries were enrolled in PDPs than in MA-PD plans—17.4 million versus 8.8 million (Figure 1).²⁹

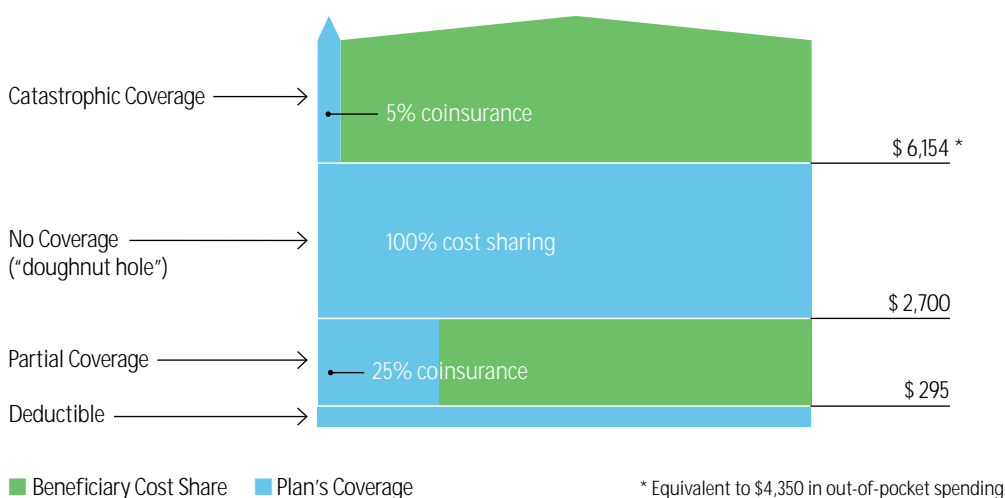
FIGURE 1. Medicare Part D Enrollment, 2009



Source: Avalere Health analysis of CMS data from January 2009.

Most beneficiaries have access to a large selection of Part D plans that vary widely in coverage, premiums, and cost sharing, but all plans approved by Medicare must offer, at a minimum, a standard level of coverage (Figure 2). Establishment of the coverage is done on an annual basis and includes an initial level of prescription drug coverage as well as protection for enrollees with extraordinarily high drug costs, also known as “catastrophic coverage.” In between the initial coverage period and catastrophic coverage, enrollees may experience a gap in coverage where they are required to pay for the entire cost of their prescription drugs out of pocket. This is known as the coverage gap or “doughnut hole.”

²⁹ Avalere Health analysis of CMS data from January 2009.

FIGURE 2. Medicare Part D Standard Benefit Design, 2009

Most private insurers who offer Part D plans use the flexibility allowed in the law to deviate from the standard benefit design, but each plan must meet the minimum standards for Part D coverage established in legislation and regulation. One such requirement states that plan offerings must be “actuarially equivalent” to, or better than, the standard benefit design. Most plans choose to create an alternative benefit design by reducing the deductible, creating different cost-sharing tiers for drugs on the plan’s formulary, or providing supplemental coverage for some drugs in the coverage gap. Because of the actuarial equivalence requirement, reducing cost sharing in one part of the benefit may require plans to increase costs in other parts of the benefit. CMS, which oversees Part D implementation, reviews plan benefit designs annually to ensure compliance with all program standards. Only plans that have met these standards gain permission to offer the Part D benefit.

Similarly, while private plans have some latitude in determining which drugs to cover on their plan’s formulary and at what cost-sharing levels, CMS reviews each Part D plan’s formulary coverage annually. CMS’ formulary review process includes an examination of the drugs included on the plan’s formulary as well as the cost-sharing tiers on which the drugs are placed and any utilization management requirements. As part of this review, CMS examines the formulary’s cost-sharing tiers “to ensure that the formulary does not substantially discourage enrollment of certain beneficiaries.”^{30,31} If a plan fails this test, the plan must revise its formulary coverage or it will not be approved to offer a Part D plan.

There are a number of initiatives in Part D focused on promoting better medication use for beneficiaries with chronic conditions, much like the goal of VBID. The most prominent include medication therapy management programs (MTMPs) and SNPs. The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 established MTMPs to optimize therapeutic outcomes of Part D enrollees with multiple chronic conditions through medication management.

30 CMS, Prescription Drug Benefit Manual, Chapter 6, Section 30.2.7. <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/R2PDB.pdf>

31 This formulary requirement is based on similar language in the Part D statute. Social Security Act, Section 1860D-11(e)(2)(D)(i).

Both PDPs and most MA-PD plans are required to have an MTMP and must target high-risk patients who have multiple chronic conditions, take multiple Part D drugs, and are likely to incur more than \$4,000 in annual drug costs.³² Because plans have wide latitude in defining eligibility criteria and services offered, current MTMP services vary widely by plan. MTMP services could include medication reviews and counseling services through educational mailings, direct phone calls, and/or face-to-face interactions with pharmacists.

Also instituted by the MMA, SNPs are a type of MA-PD plan designed to meet the needs of Medicare subpopulations that could benefit from specialized care. The MMA granted SNPs certain exceptions relative to other MA-PD plans such as the ability to limit enrollment to beneficiaries who meet one of three criteria: “dual eligibles” (those who qualify for both Medicare and Medicaid), institutionalized beneficiaries, and those with severe or disabling chronic conditions. SNPs are required to tailor their medical and drug benefits to meet the needs of the target population, ideally improving the quality of care for those enrollees and lowering overall costs. SNP enrollment has grown rapidly since the beginning of the program, from 603,000 enrollees in 2006³³ to almost 1.3 million in 2008.³⁴

Why Is VBID Not a Common Option for Medicare Part D Beneficiaries Today?

While Part D plans have the flexibility to design their benefits and formulary coverage to lower cost sharing for certain high-value drugs, few appear to do so. However, there are early indications that plans may be interested in VBID. Senior Dimensions, an MA-PD plan offered in Nevada through a subsidiary of UnitedHealthcare, announced in late 2008 that it was reducing copayments for selected maintenance medications for diabetes, chronic obstructive pulmonary disease, asthma, high blood pressure, and seizures.³⁵ Prescriptions for selected brand-name drugs that previously cost \$20 to \$30 saw copayments reduced to \$3 to \$5, similar to charges for generic drugs. Additionally, some chronic condition SNPs (CC-SNPs) may be charging lower cost sharing for drugs to treat the conditions they target.

Despite these examples, VBID is not yet prevalent in the Part D program. In this section, we discuss several reasons why more plans are not implementing VBID and suggest options for mitigating any concerns. Overall, plan concerns are likely to focus on the effects of VBID on plan enrollment and the potential return on investment. These issues are interrelated, as the relative health of a plan’s enrollees can affect the plan’s costs.

First, incorporating VBID in the Part D market where plans compete for enrollees may raise concerns about adverse selection.³⁶ A more generous benefit design, such as one that eliminates or reduces cost sharing for targeted beneficiaries or selected drugs, is likely to attract new beneficiaries with the targeted chronic condition or who take the targeted drug. Attracting sicker beneficiaries may increase a plan’s costs and ultimately result in higher premiums for all the plan’s enrollees. (SNPs may be less concerned about adverse selection than other MA-PD plans or PDPs, due to their

32 In January 2009, CMS released guidance proposing changes to MTMP eligibility criteria and required MTM services, beginning in plan year 2010. However, the agency has since withdrawn that document for further review. It is unclear at this time how MTMP eligibility, enrollment, and services might change in future years. CMS, “Medicare Part D Medication Therapy Management Programs: 2008 Fact Sheet,” March 19, 2008. <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MTMFactSheet.pdf>

33 CMS, “2006 Special Needs Plan (SNP) Enrollment Report by SNP Type.” http://www.cms.hhs.gov/SpecialNeedsPlans/Downloads/06SNP_Enrollment_by_Type11-9-06.pdf

34 CMS, Monthly SNP Reports, September 2008.

35 “Senior Dimensions Lowers Prescription Drug Co-Payments on Many Widely Used Brand-Name Maintenance Drugs.” *Business Wire*, September 24, 2008.

36 Chernew, *Health Affairs*, w199-200.

unique structure that already targets specific, high-risk populations.) Although the relative health status of each plan's enrollees form part of the basis for Part D plan payments, the risk-adjusted payments do not fully mitigate the risk of adverse selection. Even in the short history of the Part D program, several plan sponsors have eliminated more generous benefits such as gap coverage because of adverse selection. Revisions to the current risk-adjustment system or additional risk-adjusted payments may encourage more widespread adoption of VBID in the Part D program.

Another way to reduce the risk of adverse selection is to require that all Part D plans offer the same coverage for the targeted beneficiaries or drugs. If all plans covered the targeted conditions or drugs equally, no individual plan would be at greater risk for attracting high-risk beneficiaries than any other plan. However, this standardized approach may have unintended consequences, and should be carefully considered. Requirements that standardize Part D plans' coverage of certain drugs limits plans' ability to negotiate with pharmaceutical manufacturers for lower prices, and could increase overall costs to the Part D program. Additionally, limits on plan flexibility in offering the benefit could negatively affect plans' interest in participating in the Part D program.

Second, plans may be concerned that reducing cost sharing for some beneficiaries or drugs may require plans to increase cost sharing for other drugs or raise premiums in order to remain actuarially equivalent to the standard Part D benefit. Plans may be hesitant to raise premiums, however, and risk losing enrollment if members leave the plan for other, lower-premium options. The risk of losing market share in the competitive Part D market could be a disincentive for plans to implement VBID.

Third, standalone PDPs, which offer drug benefits only, currently lack the financial incentives to incorporate VBID into their benefit designs. Reducing cost sharing for drugs will not only increase drug costs, as noted above, but provides no return on investment for these plans. While MA-PD plans, which cover both drugs and medical services, may gain some return on investment from VBID through reduced hospitalizations or emergency care, PDPs are not able to realize offsets in non-drug spending associated with more drug adherence. To encourage PDPs to adopt VBID, significant incentives would be required.

MA-PD plans are likely to have fewer concerns about higher drug costs than PDPs, because MA-PD plans could realize savings in the medical benefit if enrollees remain healthier because of improved medication adherence. Though some studies have demonstrated that medication adherence lowers total medical costs,³⁸ there is little research specifically measuring the impact of VBID on medication adherence and outcomes in the Medicare population. Due to this lack of research in the Part D population, MA-PD plans may be reluctant to adopt VBID, absent additional incentives. MA-PD plans convinced of the potential for VBID in this population may be concerned that any potential cost savings available from better medication adherence would accrue to another plan if the enrollee chooses to switch plans, as Part D beneficiaries are allowed to do each year.³⁹ This concern may not be as great in Part D as in the commercial market, because only a small percentage of Part D beneficiaries switch plans each year.⁴⁰ However, MA-PD plans may need to be reassured

37 "Sierra to Incur Loss on Enhanced Medicare Part D Prescription Drug Product Offering." *Business Wire*. http://findarticles.com/p/articles/mi_m0EIN/is_2007_Feb_27/ai_n27306987

38 Thomas, AARP Public Policy Institute.

39 CMS allows dual-eligible beneficiaries to change plans monthly, and has designated special enrollment periods to allow other subgroups of beneficiaries to change plans throughout the year.

40 About 6 percent of beneficiaries changed Part D plans in 2008 (excluding low-income beneficiaries). CMS Press Release, "Medicare Prescription Drug Benefit's Projected Costs Continue to Drop." January 31, 2008.

that they will benefit from their investment in VBID, potentially through incentives similar to those offered to PDPs.

Incentives to plans for incorporating VBID into their benefit designs could take several forms. Financial incentives would provide additional payments to plans that incorporate VBID, to offset the potential costs of reducing copays. Legislation may be required to offer financial incentives, or CMS could pursue this approach using its demonstration authority. Additional risk-adjusted payments or financial incentives for all Part D plans based on enrollees' adherence to drug regimens could encourage the use of VBID in their benefit designs.

CMS could also offer non-financial incentives to encourage greater VBID adoption. For example, CMS currently uses a star rating system on its Medicare Prescription Drug Plan Finder to rate Part D plans' performance on a number of measures. CMS could add information to denote which plans include VBID in their benefit designs. CMS could also change its Part D marketing rules to highlight the use of VBID. New marketing rules allowing plans to discuss their use of VBID as a differentiator from other plans, or allowing pharmacists to educate beneficiaries on plans using VBID, could provide plans a marketing advantage that may increase enrollment, encouraging the use of VBID in Part D benefits. However, marketing based on VBID could exacerbate adverse selection concerns. The best course is to consider both issues in tandem. Finally, CMS could offer plans additional flexibility on other Part D requirements, such as the six protected classes, in exchange for incorporating VBID into their benefit designs. In any incentive program offered solely to plans incorporating VBID, Congress or CMS would have to establish clear standards defining VBID approaches that would qualify for the incentives.

Options for Implementing VBID in Medicare Part D

While designing an incentive program to encourage Part D plans to adopt VBID will be an important task for policymakers, the first step toward more widespread VBID adoption is to identify how plans could integrate a VBID approach into their benefit designs. In general, plans can employ VBID by targeting certain populations or identifying particular medications – the two most common approaches for implementing VBID in the private sector. Our analysis of the Medicare Part D program’s structure identified five options discussed below and in Table 2.

TABLE 2. Summary of VBID Policy Options in Medicare Part D

Policy Options	Description
1. Reduce Cost Sharing for Specific Drugs or Drug Classes	Low or no cost sharing for high-value drugs would encourage adherence among all enrollees who may benefit from a drug, regardless of their chronic condition diagnosis
2. Exempt Specific Drugs or Drug Classes from 100% Cost Sharing in the Coverage Gap	Because adherence may decline as enrollees are exposed to high cost sharing, this option would offer protection when costs are generally the greatest – during the coverage gap
3. Reduce Cost Sharing for Enrollees with Chronic Conditions	Targeting enrollees with a specific chronic condition for lower cost sharing – for all drugs or just those that treat the particular condition – would lessen the out-of-pocket burden associated with that chronic condition
4. Reduce Cost Sharing for Enrollees Participating in MTMPs	Enrollees participating in Part D’s medication management program would benefit from reduced cost sharing for specific drugs, in addition to other patient outreach and counseling on medication use
5. Reduce Cost Sharing for CC-SNP Enrollees Based on the Plan’s Target Condition	SNPs targeting particular chronic conditions could reduce cost sharing for drugs that treat the target condition as part of an overall model of care aimed at managing the chronic condition

Option 1: Reduce cost sharing for specific drugs or drug classes. Part D plans—both PDPs and MA-PD plans—could lower cost sharing for medications with high clinical value relative to other drugs on the formulary. This approach would benefit all enrollees who take the targeted drugs, regardless of diagnosis. Additionally, plans could target any high-value drugs or drug classes and would not necessarily choose drugs to treat a single chronic condition. Plans could place these high-value drugs on an existing formulary tier that ensures minimal cost sharing—such as a low-cost tier traditionally reserved for generic drugs—or create a separate tier that would be limited to the high-value drugs identified by the plan.

Option 2: Exempt specific drugs or drug classes from 100 percent cost sharing in the coverage gap.

Plans could provide coverage for high-value drugs during the coverage gap. This option could simply extend coverage of these high-value drugs through the coverage gap or work in combination with Option 1 to offer low cost sharing for the targeted drugs throughout the benefit year.

Option 3: Reduce cost sharing for enrollees with chronic conditions. Plans could target enrollees diagnosed with certain chronic conditions, and lower cost sharing for high-value drugs that treat the particular condition for those enrollees. A variation of this option is to lower cost sharing on all drugs for enrollees with the targeted chronic conditions. In order to do this, plans would have to implement processes for identifying qualified patients based on diagnosis. Unlike Option 1, low cost sharing—either for high-value drugs or for all drugs—would be available only to patients diagnosed with certain conditions identified by CMS or the plan. Though this option may affect fewer beneficiaries than Option 1, it may reduce implementation costs due to its more targeted approach. For example, reducing cost sharing for ACE inhibitors for patients with diabetes may allow this population to control their chronic condition better than reduced cost sharing for diabetes medications alone,⁴¹ and would be less costly for plans than reducing cost sharing for all patients taking ACE inhibitors. The ability to more appropriately target interventions using this VBID approach may be more cost-effective and could lead to better outcomes than options that target specific drugs or drug classes.⁴²

Option 4: Reduce cost sharing for enrollees participating in MTMPs. This option is an alternative to targeting enrollees for VBID by instead identifying patients who are participating in an MTMP. MTMP enrollees would have access to lower cost sharing for high-value medications treating their chronic conditions, in addition to receiving MTMP-related services, a combination that has the potential to improve adherence and outcomes significantly.

Option 5: Reduce cost sharing for CC-SNP enrollees based on the CC-SNP's target condition.

While the previous four approaches to VBID can work in PDPs or MA-PD plans, CC-SNPs—a unique type of MA-PD plan—have a particular advantage for using VBID: CC-SNPs already target enrollment to Medicare beneficiaries with particular chronic conditions. In Option 5, CC-SNPs would reduce or eliminate cost sharing for specific drugs or drug classes that treat the plan's targeted chronic conditions.

41 Rosen, *Ann Intern Med*.

42 Chernew, *Health Affairs*.

Analysis of Options

We evaluated the feasibility of each of our five policy options based on four criteria: 1) potential size of the Medicare Part D population affected; 2) CMS' authority to change policy within existing statute and regulation; 3) requirements for implementation; and 4) political support.

Potential Size of the Medicare Part D Population Affected

To assess each option's potential impact on the Medicare Part D program, we estimated the number of people affected and the potential change in beneficiaries' health outcomes. For the purposes of this analysis, we make certain assumptions based on current literature and research on VBID and chronic conditions. For options that target specific chronic conditions, we use diabetes to estimate the relative size of the affected population. For options that target specific drugs, we use oral hypoglycemics and insulin as examples, because only diabetics use these classes of drugs. However, diabetics may use other classes of drugs to manage their condition and comorbidities, and plans targeting specific drugs through VBID are not limited to drugs used to treat a single condition. While all of the options can apply to a much broader range of chronic conditions or drugs, the selection of a single condition conveys a sense of the magnitude of the impact an option could have if applied uniformly in the Part D program. (For additional information on why we focus on diabetes, see Section II, Methodology.)

Additionally, to assess the full potential of VBID within Medicare Part D, we assume that all Part D plans take advantage of this opportunity. Finally, we base our estimates on current Part D market and enrollment trends. Dramatic changes in plan offerings or beneficiary enrollment could alter certain outcomes of this analysis. These assumptions allow for illustration of the impact of a VBID approach on beneficiaries with diabetes, but may not reflect the actual number of beneficiaries affected if other conditions or drugs gain selection for lower cost sharing.

It is also important to note that reduced cost sharing through VBID will have a limited impact on beneficiaries who qualify for the low-income subsidy (LIS). LIS-eligible beneficiaries pay a standard copayment amount for Part D drugs, unless their plan's cost sharing is below that amount. For example, LIS-eligible beneficiaries in 2009 are responsible for cost sharing of no greater than \$2.40 for generic drugs and \$6 for brand-name medications;⁴³ if a plan charges lower copayments than the LIS amount, the beneficiary pays the lower copayment.⁴⁴ LIS-eligible beneficiaries enrolled in plans implementing VBID by eliminating cost sharing or reducing it below the LIS amounts will be able to benefit from VBID, but those enrolled in plans whose reduced cost sharing is above the LIS amounts will not. Due to this uncertainty, our estimates in this section include all beneficiaries, regardless of LIS eligibility, unless otherwise noted.

Based on our analysis and the available literature, Options 1 and 3, which would implement VBID through a reduction of cost sharing for specific drugs or enrollees with chronic conditions may reach the greatest number of Medicare beneficiaries (Table 3). A more detailed discussion of how we derived these estimates follows.

43 CMS, Prescription Drug Benefit Manual, Chapter 13, Appendix A. <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/R7PDB.pdf>

44 CMS Final Rule, CMS 4131-FC. Issued January 12, 2009. <http://edocket.access.gpo.gov/2009/E9-148.htm>

TABLE 3. Relative Size of Medicare Population Affected by Each Option

Policy Options	Estimated Number of Beneficiaries with Diabetes Affected*
1. Reduce Cost Sharing for Specific Drugs or Drug Classes	6 Million
2. Exempt Specific Drugs or Drug Classes from 100% Cost Sharing in the Coverage Gap	2 Million
3. Reduce Cost Sharing for Enrollees with Chronic Conditions	6 Million
4. Reduce Cost Sharing for Enrollees Participating in MTMPs	<2 Million**
5. Reduce Cost Sharing for CC-SNP Enrollees Based on the Plan's Target Condition	<268,000**

* Diabetes is used as an example of a chronic condition; oral hypoglycemics and insulin are used as the drug classes that each policy option may target. However, each option could apply to any number of conditions, drugs, or drug classes, and changes to the targeted conditions or drugs could increase or decrease an option's impact.

** Due to the lack of data on the number of beneficiaries with diabetes enrolled in MTMPs and SNPs, estimates reflect total number of beneficiaries in these programs.

Option 1: If plans implementing Option 1 reduce cost sharing for oral hypoglycemics and insulin, the number of beneficiaries affected will be nearly the same as the number of beneficiaries with diabetes, because only diabetics take those drugs. About 24 percent of the Medicare population,⁴⁵ or approximately 6 million Part D enrollees, have diabetes. If Part D plans were to expand Option 1 to include specific classes of drugs taken by diabetics and non-diabetics, such as antihypertensives or cholesterol-lowering drugs, the number of beneficiaries affected would rise substantially.

Option 2: In 2009, the coverage gap applies to beneficiaries with total drug spending above \$2,700 and lasts until they reach \$4,350 in annual out-of-pocket spending.⁴⁶ In a previous study, Avalere estimated that 43 percent of PDP enrollees with diabetes and 33 percent of those in MA-PD plans reached the coverage gap in 2006.⁴⁷ A similar study by the Kaiser Family Foundation found that number to be more than half.⁴⁸ Both of these studies exclude at least 1.6 million beneficiaries with diabetes who qualify for the LIS, which protects beneficiaries from the coverage gap.⁴⁹ If applying these percentages to the total 4.4 million non-LIS Part D beneficiaries with diabetes, this VBID option would likely affect approximately 2 million diabetes patients.

45 Tan, Academy Health.

46 CMS, Prescription Drug Benefit Manual, Chapter 5, <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDMChap5BeneProtections.pdf>

47 Avalere Health, "The Impact of Medicare Part D on Beneficiaries with Type 2 Diabetes/ Drug Utilization and Out-of-Pocket Costs." March 2008. www.avalerehealth.net

48 Hoadley, J, et al. "The Medicare Part D Coverage Gap: Costs and Consequences in 2007." Henry J. Kaiser Family Foundation (August 2008).

49 Approximately 1.6 million beneficiaries with diabetes are dual eligibles who qualify for Medicare and Medicaid; additional non-Medicaid Part D beneficiaries may also be exempt from 100 percent cost sharing in the coverage gap due to their eligibility for the LIS. Kaiser Commission on Medicaid and the Uninsured, "Dual Eligibles and Medicare Part D." May 2006. www.kff.org

Option 3: All Part D enrollees with the targeted chronic condition would benefit from VBID in this option. For diabetes, this represents approximately 6 million Part D enrollees.⁵⁰

Option 4: CMS has reported that approximately 8 percent of beneficiaries, or 2 million people, participated in MTMPs in 2007.⁵¹ Since MTMPs include beneficiaries with other chronic conditions, the number of beneficiaries with diabetes would be lower than 2 million. In addition, this option would affect relatively fewer beneficiaries than targeting all beneficiaries with diabetes. However, linking VBID to MTMP participation could boost MTMP enrollment; in 2007, 7 percent of eligible beneficiaries did not participate in their MTMP.⁵² Additionally, efforts to increase the scope of medication-related services provided through MTMPs, coupled with VBID, could have a greater impact on beneficiary healthcare utilization and spending.

Option 5: In 2009, almost 268,000 beneficiaries enrolled in CC-SNPs.⁵³ Many CC-SNPs in 2009 target diabetes; some include diabetes and other chronic conditions, and some focus solely on diabetes. However, beginning in 2010, CMS will require that CC-SNPs target only one of a selection of chronic condition categories, including diabetes.⁵⁴

CMS Authority to Change Policy

We analyzed each policy option to determine any existing statutory hurdles that CMS may face and the regulatory or legislative changes that would be necessary to implement the suggested VBID approach.

The necessary changes fall along a spectrum from options requiring new legislation to options that CMS can execute administratively under the current law, and those that plans can do today without any policy changes. Based on our analysis, Part D plans can implement Options 1, 2, and 5 in the current policy environment, while Options 3 and 4 may require legislative changes (Table 4). A more detailed discussion of the legislative and regulatory hurdles we uncovered follows.

50 Tan, Academy Health.

51 CMS, "Medicare Part D Medication Therapy Management Programs 2008 Fact Sheet." <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MTMFactSheet.pdf>

52 Ibid.

53 Avalere Health analysis of CMS' SNP Monthly Enrollment File, January 2009.

54 CMS, "Special Needs Plan Chronic Condition Panel 2008 Final Report." November 12, 2008. <http://www.cms.hhs.gov/specialneedsplans/>

TABLE 4. Policy Changes Required for Implementation

Policy Options	Likely Policy Change Needed
1. Reduce Cost Sharing for Specific Drugs or Drug Classes	No policy change necessary, but additional incentives may be required to promote greater adoption
2. Exempt Specific Drugs or Drug Classes from 100% Cost Sharing in the Coverage Gap	No policy change necessary, but additional incentives may be required to promote more gap coverage options that cover high-value drugs
3. Reduce Cost Sharing for Enrollees with Chronic Conditions	Examine application of non-discrimination clause; may require exemption through regulation or legislation Exempt VBID from uniform benefit requirement through regulation or legislation
4. Reduce Cost Sharing for Enrollees Participating in MTMPs	Examine application of non-discrimination clause; may require exemption through regulation or legislation Exempt VBID from uniform benefit requirement through regulation or legislation
5. Reduce Cost Sharing for CC-SNP Enrollees Based on the Plan's Target Condition	No policy change necessary; some CC-SNPs may already be doing this

Option 1: No policy change required, but incentives may be needed. Part D plans currently have the ability to place covered drugs on different formulary tiers with varied cost sharing for each tier. Through this ability, plans could place high-value drugs or drug classes on lower cost-sharing tiers to provide better access to those drugs for their members. Plans can implement VBID by reducing or eliminating cost sharing for specific drugs as long as a plan's formulary continues to meet CMS' formulary guidelines, rules on actuarial equivalence, and other applicable Part D standards.

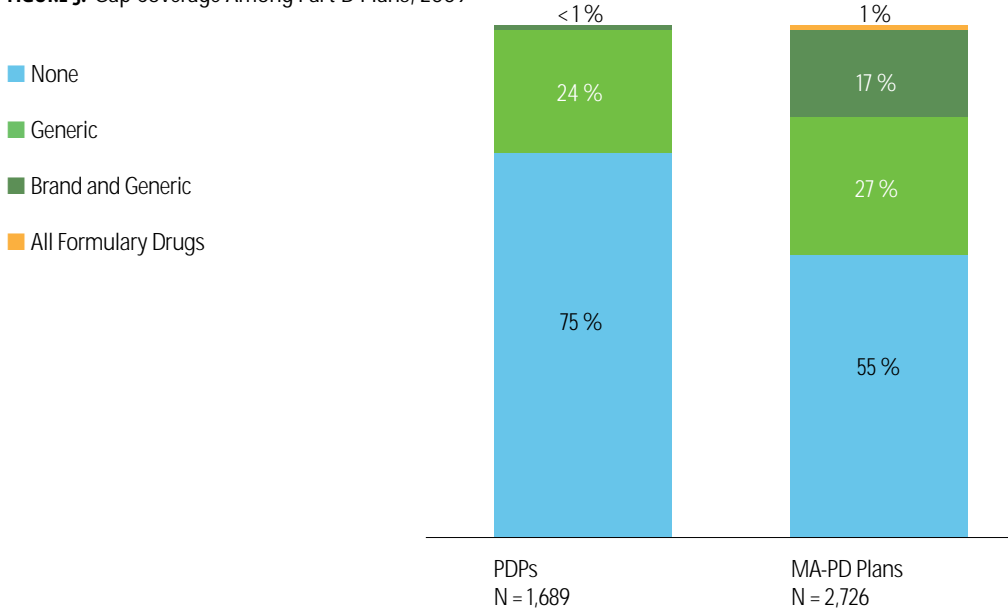
As noted above, at least one MA-PD plan began exercising this option in 2008, but most Part D plans do not appear to be implementing VBID. In order to encourage more Part D plans to feature a VBID approach similar to Option 1, CMS officials could highlight this type of benefit design as one that is not only acceptable but could result in improved health outcomes for beneficiaries. CMS could make such a statement through its regular communications with Part D plans, via press release, or in subregulatory guidance such as the annual Call Letter or the Medicare Prescription Drug Benefit Manual. Additionally, to encourage plans, particularly PDPs, to adopt this option supplemental payments or non-financial incentives, such as those discussed in Section III, may have a role.

Option 2: No policy change required, but incentives may be needed. Similarly, Option 2 is currently available to Part D plans wishing to cover certain drugs through the coverage gap. In order to do so, the plan must offer an enhanced benefit design including gap coverage. Plans can choose which formulary drugs are eligible for gap coverage by the plan, and could select high-value drugs or drug classes for this coverage. Beneficiaries in these plans would pay the same cost-sharing amount for the selected drugs in the initial coverage period until they reach the catastrophic limit.

In 2009, 25 percent of PDPs and 44 percent of MA-PD plans offer gap coverage to beneficiaries, but most of these cover only generics in the gap (Figure 3). Among standalone PDPs, only three plans

cover any brand-name drugs in the coverage gap in 2009. MA-PD plans, which could benefit from better health outcomes and lower medical costs for beneficiaries with improved adherence, are more likely to cover brands in the gap; 17 percent do so in 2009. As with Option 1, plans may be reluctant to implement Option 2 without encouragement from CMS as well as specific incentives.

FIGURE 3. Gap Coverage Among Part D Plans, 2009



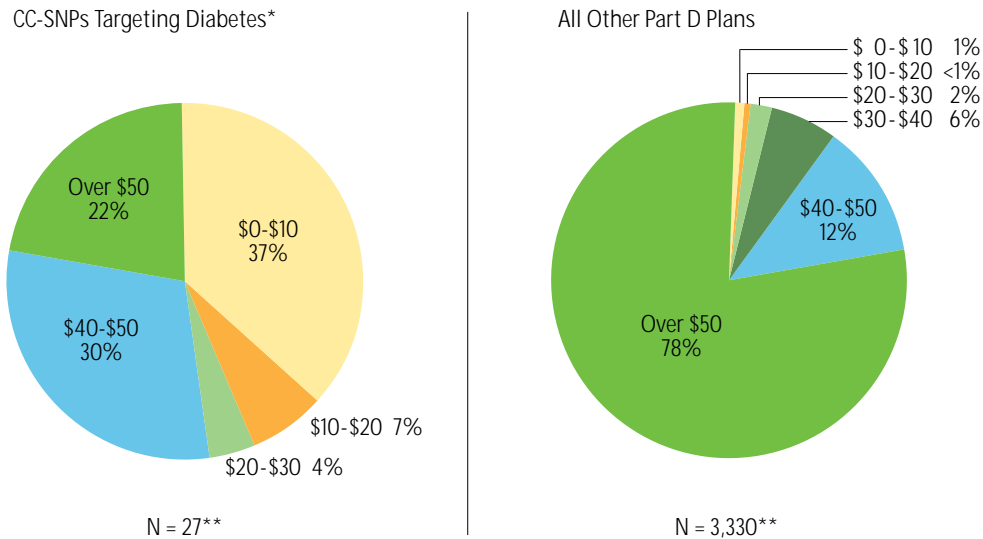
Source: Avalere Health analysis using Data Frame®, a proprietary database of Medicare Part D plan features and 2009 PDP and MA-PD plan data released September 25, 2008, by CMS.

Option 5: Within existing CMS authority. Under current policy, CC-SNPs would likely be allowed – perhaps encouraged – to adopt VBID for the drugs used to treat the plan’s target condition. The purpose of CC-SNPs is to provide specialized care for their target populations. Lowering cost sharing for the targeted chronic condition may be one method CC-SNPs can use to demonstrate their focus on beneficiaries with that condition. This may prove especially valuable as the SNP program is currently set to expire on January 1, 2011, and policymakers are scrutinizing SNPs to determine whether they actually provide more targeted care and improve enrollees’ health status compared to other types of MA-PD plans.

A limited analysis indicates that some diabetes SNPs may be using this approach in their 2009 benefit designs.⁵⁵ Thirty-two of the 209 CC-SNPs offered in 2009 exclusively target beneficiaries with diabetes, while many others target diabetes along with other conditions.⁵⁶ In examining 28 of these SNPs’ formularies, nearly half charge copayments of \$30 or less for all of the diabetes drugs they cover (Figure 4). In comparison, fewer than 4 percent of other Part D plans (including non-SNPs) have such low copayments for all of their covered diabetes drugs. While this small sample is not representative of all CC-SNPs’ formularies, it may indicate an interest in charging lower cost sharing for drugs that treat the CC-SNP’s targeted condition.

⁵⁵ Avalere Health analysis using Data Frame®, a proprietary database of Medicare Part D plan features and 2009 PDP and MA-PD plan data released September 25, 2008, by CMS.

⁵⁶ Avalere Health analysis of CMS’ SNP Monthly Enrollment File, January 2009.

FIGURE 4. Highest Copayments for Covered Diabetes Drugs, 2009

Source: Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. Data from November 2008 reflecting 2009 plans. Graphics represent the copayment range for each plan's highest formulary tier containing a drug used to treat diabetes. *Chronic Condition Special Needs Plans that exclusively target diabetes. **Analysis excludes 1 CC-SNP and 721 other Part D plans whose highest tier for diabetes drugs requires coinsurance.

As an additional incentive for CC-SNPs to incorporate VBID in their benefit designs, CMS could define Option 5 to help CC-SNPs meet the requirement that they design a model of care “to meet the specialized needs of the SNP target population.”⁵⁷ The model of care requirement was established by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), and CMS released further guidance in an interim final rule that has not yet been finalized. In this regulation, CMS indicated that it would not “endorse any particular set of evidence-based guidelines or protocols,” but provides examples of the elements each SNP should include in its model of care, including care coordination services and a network of specialized providers.^{58, 59} CMS could add more examples of elements of a SNP model of care, including VBID, through further regulation or guidance.

Options 3 and 4: Exceptions to ‘Uniform Benefit’ requirement may be required. Options 3 and 4 each propose to implement VBID by identifying a subgroup of Part D beneficiaries and reducing cost sharing for only those beneficiaries. In both of these scenarios, enrollees in a Part D plan will face differences in cost sharing for the same drugs based on whether the enrollee is a member of the target population. Allowing differences in benefit design for beneficiaries within the same plan may require legislative and regulatory changes. Legislation specifically defining this VBID approach and exempting such benefit structures from the antidiscrimination and uniform benefit provisions would most clearly establish the authority of CMS to approve plan bids using VBID approaches that target a subset of plan beneficiaries.

57 CMS, Interim Final Rule CMS 4138-IFC, issued September 15, 2008.

58 Ibid.

59 CMS has provided additional discussion on the model of care requirement in subregulatory guidance documents, including the 2008 and 2009 Call Letters. CMS, Contract Year 2008 Call Letter, April 19, 2007, and CMS, Contract Year 2009 Call Letter, March 17, 2008. <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf>

The nondiscrimination clause, which prevents Part D plans from designing a benefit that “substantially discourag[e]s enrollment of certain beneficiaries,”⁶⁰ may be seen as an obstacle to VBID approaches that target a subset of plan enrollees. While the VBID design may encourage enrollment of some beneficiaries, it is possible that a formulary structure that reduces cost sharing for certain beneficiaries but not others may be interpreted as violating this provision. For example, a plan that charges lower cost sharing for beneficiaries with diabetes could be viewed as “substantially discouraging” the enrollment of beneficiaries who do not have diabetes. Legislation to allow VBID could clarify the parameters of a benefit design that targets certain beneficiaries as an exception to this provision.

Additionally, a legislative change to authorize Options 3 or 4 should address the Part D requirement that plans provide a uniform benefit to all enrollees. In final regulations implementing the Part D program, CMS describes requirements for prospective Part D plans, including a requirement that each plan “must reflect a uniform benefit package, including premium... and all applicable cost sharing, for all individuals enrolled in the plan.”⁶¹ In the preamble to this regulation, CMS explains: “This means that all enrollees in a given PDP or MA-PD plan will be subject to the same cost sharing structure and will be charged the same premium for benefits the PDP sponsor or MA organization chose to offer.”⁶² CMS based this regulation on a provision of the MMA that requires plans to charge all beneficiaries a uniform premium amount.⁶³ While the legislative language on the uniform benefit does not specifically require equivalent cost sharing for all enrollees, CMS would have to revise its regulatory language to allow VBID targeting certain beneficiaries. CMS could also consider using its demonstration authority to allow these options.

60 Social Security Act, Section 1860D-11(e)(2)(D)(i).

61 CMS, Final Rule 42 CFR 423.265(c) issued October 1, 2007. http://edocket.access.gpo.gov/cfr_2007/octqtr/pdf/42cfr423.265.pdf

62 CMS, Final Rule, CMS-4068-F, issued January 28, 2005. <http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/CMS4068F.PDF%20>

63 Beneficiaries who are eligible for the low-income subsidy or charged a late enrollment penalty are permitted to have different premiums and/or cost sharing than other enrollees. CMS, MMA 1360D -13(a)(1)(F).

Ability to Implement Options

Given the high likelihood for the implementation of VBID in Medicare Part D, certain operating processes may need to be altered. This section discusses some of the operational changes that may be required. A summary of the implementation issues we identified with each option appear in Table 5.

TABLE 5. Operational Changes Required for Implementation

Policy Options	Likely Operational Change Needed
1. Reduce Cost Sharing for Specific Drugs or Drug Classes	Plans may create new formulary tier for targeted drugs
2. Exempt Specific Drugs or Drug Classes from 100% Cost Sharing in the Coverage Gap	Plans must offer gap coverage for targeted drugs Plans may create new formulary tier for targeted drugs
3. Reduce Cost Sharing for Enrollees with Chronic Conditions	Process to identify enrollees with particular chronic condition diagnoses and to select drugs eligible for reduced cost sharing
4. Reduce Cost Sharing for Enrollees Participating in MTMPs	Ability to monitor participation in MTMPs
5. Reduce Cost Sharing for CC-SNP Enrollees Based on the Plan's Target Condition	None

Each option identifies certain beneficiaries or drugs for reduced cost sharing. Identifying which beneficiaries and/or which drugs, if not specified by authorizing legislation, may be left to CMS or another entity to determine, or could be left to individual plans to decide. In the event that policymakers wish to establish a standardized set of drugs or conditions to target with VBID, legislation or regulations could name particular conditions, drugs, or drug classes for targeting. Alternatively, policymakers could establish a process for determining the targeted conditions or drugs, similar to the process CMS used to determine the chronic conditions for which plans could create CC-SNPs. However, once that level of detail is established, CMS may need to provide plans with additional guidance, particularly if the VBID approach targets beneficiaries who meet certain criteria.

Options 1 and 2, which focus on specific classes of drugs, may have few implementation issues once the identification of targeted classes of drugs occurs. In Option 1, plans could create a new formulary tier with low or no cost sharing exclusively for the targeted drugs, or place those drugs on their existing lowest-cost tier. To implement Option 2, a plan would have to change its offering to include gap coverage for the targeted drugs or drug classes by adding gap coverage where not offered or adding high-value drugs to the list of drugs included in a plan's gap coverage.

Option 3 requires plans to identify enrollees with certain diagnoses. Part D plans already estimate their enrollees' particular diagnoses and their severity on an aggregate level, which determines the risk-adjusted payments CMS makes to each plan. Plans could work with CMS to assign these risk scores at an individual level and use those codes as a proxy for beneficiaries' chronic conditions to determine a beneficiary's eligibility for reduced cost sharing. Alternatively, plans could verify eligibility through a note from the patient's provider, similar to the verification process that CC-SNPs employ, but this method would impose a high administrative burden on plans and be costly to implement.

In Option 4, plans would be required to identify enrollees who are participating in their MTMP. Though initial identification may be straightforward, MTMP participants may disenroll during the benefit year, and plans may wish to monitor participation to limit the number of enrollees who benefit from low cost sharing but no longer participate in their MTMP. Individual Part D plans or CMS could establish a process for determining a beneficiary's participation in the program, potentially several times during the year, to ensure he or she continues to qualify for low cost sharing.

For Options 3 and 4, CMS and plans may need to overcome operational challenges in determining which cost-sharing amount each enrollee must pay for each prescription. Under the current system, all beneficiaries within a plan pay the same amount for a given drug unless they qualify for the LIS. Under Options 3 and 4, plans must track which beneficiaries qualify for lower cost sharing and which do not, and charge the appropriate cost sharing for each enrollee's drugs. It may be possible to develop a process similar to the one used to track LIS cost sharing to manage this task.

Option 5 may require CMS to identify standards for VBID necessary for fulfilling the model of care requirement, and compare CC-SNP formularies to those standards in the formulary review process.

Political Support

The VBID approaches described in this paper provide exciting opportunities for policymakers to address the realities of spiraling healthcare costs and suboptimal quality, issues of great importance to their multiple constituencies. Over the past two years, a diverse group of stakeholders across the healthcare enterprise has expressed support for this concept. Because the percentage of health services with unequivocal clinical evidence to support their use under VBID programs is small in relation to aggregate medical expenditures, even groups that might typically oppose such efforts as "paternalistic" have been receptive to this idea.

Patient advocacy groups representing individuals with chronic conditions who are concerned about high cost sharing in Medicare Part D are likely to support VBID in general, and the more likely their members are to benefit from VBID, the stronger their support will be. Pharmaceutical manufacturers appear to support VBID in concept but have particular interest in how value is determined. Health plans tend to encourage Part D policies that provide additional flexibility in benefit designs, and are likely to show interest in VBID in Medicare, as an extension of the concept's rapidly growing presence in the private sector.

Political interest in Option 5 is likely to be strong, as discussed in previous sections. While it appears that some CC-SNPs may be using a VBID approach in their current benefit designs, integrating VBID into more of these plans provides CC-SNPs an opportunity to offer more specialized benefits for their target population, demonstrate significant differences from other Part D plans, and potentially gather data on the impact of VBID on Medicare beneficiaries' adherence and health outcomes.

Similarly, policymakers are likely to view Options 1 and 2 positively, since Part D plans can implement both options in the current program. In fact, CMS noted in its Part D regulations that plans should consider the impact on total medical costs when deciding how to cover drugs on their formularies: "For example, to the extent that a particular drug has been shown to be more effective in preventing the need for hospital care or better at controlling acute flare-ups requiring the use of other services, we expect [plans] to take these things into account in their determinations of drug efficacy."⁶⁴

64 CMS, Final Rule, CMS-4069-F, issued January 28, 2005.

While Options 3 and 4 may appear promising, they are likely to be less attractive to policymakers due to the possible changes to legislative and regulatory policies, particularly the uniform benefit provision. Additionally, policymakers may be reluctant to adopt Option 4 due to potential policy changes regarding MTMP participation. MTMPs are still evolving in Part D, and CMS has indicated an interest in changing guidance related to the structure of and services provided by these programs.

Overall, political support for VBID appears to be strong, bipartisan, bicameral, and growing. The policy changes identified in this paper provide a roadmap for several scenarios that will advance VBID principles in efforts to improve health and contain costs.

Conclusion

Based on this analysis, it appears that several options could be successful vehicles for VBID in Medicare Part D and immediately implemented (Table 6). In particular, Option 1 targeting specific drugs or drug classes is an option for plans in the current policy environment, and has the potential to reach a large number of Part D beneficiaries. Option 2 is also presently available to plans and, while affecting fewer beneficiaries, it targets those patients with high annual drug spending who may benefit most from this type of intervention. As more evidence of the benefits of VBID becomes available, policymakers may wish to pursue legislative changes that would create new incentives to encourage more Part D plans to adopt these types of benefits.

TABLE 6. Summary of Analysis

Policy Options					
	Option 1: Reduce Cost Sharing for Specific Drugs or Drug Classes	Option 2: Exempt Specific Drugs or Drug Classes from 100% Cost Sharing in the Coverage Gap	Option 3: Reduce Cost Sharing for Enrollees with Chronic Conditions	Option 4: Reduce Cost Sharing for Enrollees Participating in MTMPs	Option 5: Reduce Cost Sharing for CC-SNP Enrollees Based on the Plan's Target Condition
Potential to Improve Medicare					
Size of Medicare Population Affected	●	◐	●	◐	○
Feasibility					
CMS Authority to Change Policy	●	●	○	○	●
Ability to Implement Policy	●	●	○	◐	●
Political Support	●	●	◐	◐	●

● Greatest Potential / Most Feasible ◐ Moderate Potential / Feasibility ○ Least Potential / Feasible

Option 5 is also feasible in the current policy environment. However, targeting VBID to enrollees in CC-SNPs will have a limited impact on the Medicare population – currently about 268,000 beneficiaries, only 1 percent of Part D enrollment. Due to the small scale of this option's impact, Option 5 may be an ideal first step in implementing VBID in the Medicare Part D program. CMS and policymakers could encourage CC-SNPs to incorporate VBID into their benefit designs and to collect data on adherence and outcomes for their enrollees. As CC-SNPs gather evidence on the value of VBID in this population, policymakers could consider additional methods for incorporating VBID into the Medicare Part D program more broadly.

Option 4 also presents an interesting opportunity to demonstrate the value of VBID, despite potential legislative challenges in authorizing such an option. The pairing of MTMPs' services focused on appropriate medication use with lower cost sharing through VBID appears to have high potential to impact beneficiaries' adherence and outcomes. Lowering or removing the financial barriers to medication use will enhance medication management; conversely, MTMP services such as counseling by pharmacists could greatly improve VBID's success in improving adherence and outcomes. While a small number of Part D enrollees take part in MTMPs at present, one could argue that MTMP participants are those in the greatest need of an intervention such as VBID. Policymakers may be interested in examining this option further to determine the impact on health outcomes and overall program spending.

Finally, while Option 3 has the potential to reach a large number of Part D beneficiaries and could be a cost-effective approach to implementing VBID, the legislative and regulatory changes likely required may be barriers to its implementation, making this a less attractive option.

Discussion and Implications

This paper presents several viable options for the Medicare program to implement VBID in Part D. Policymakers have become increasingly interested in VBID as the evidence base for the merit of VBID in the private sector becomes clearer and Medicare faces continued pressure to get more value from the federal dollars spent. Each of these options have their own strengths and weaknesses based on how many Medicare beneficiaries may benefit and how easily the particular VBID approach could be implemented by Congress, CMS, and health plans. Each of these factors is dynamic and our option evaluations are sensitive to changes in the Medicare Part D market.

The scope and purpose of this paper result in various limitations that could be the focus of future analyses. First, this paper does not focus on the incentives Part D plans may require to adopt VBID. While we discuss the need for such incentives and offer several examples of incentives that policymakers could offer, this topic requires further research. Discussions with Part D plans about their interest and concerns about VBID, and feedback on the incentives that might be most attractive to plans would help to further inform policymakers interested in encouraging VBID.

Second, though this paper suggests VBID for high-value drugs and particular chronic conditions, it does not explicitly recommend what those drugs or conditions should be. While we use diabetes as an illustrative example of an appropriate condition, others may also be viable. It is also important to note that while some options target beneficiaries with specific chronic conditions, doing so is not required for VBID implementation. Options 1 and 2, for example, could target any drugs or drug classes determined to provide high value.

Third, this paper does not attempt to project costs or savings from VBID implementation. To do so with any accuracy will require more specific analysis of a particular VBID proposal. The potential cost or savings of legislative proposals will play a substantial role in determining an option's feasibility. While a quantitative analysis is not included in this paper, Avalere Health and the University of Michigan VBID Center are collaborating on a companion piece that estimates the potential impact of VBID in Medicare Part D.

In addition, this paper does not discuss the measurement or evaluation of VBID after implementation. When incorporating VBID into Medicare Part D, policymakers should also consider providing resources for measuring impact, allowing stakeholders to evaluate successes and drawbacks.

Although this analysis focused on the application of VBID to chronic condition medications covered under Medicare Part D, there is promise for VBID in other aspects of Medicare. Alternative applications of VBID within Medicare could include lower cost sharing for high-value hospital and provider services covered under Medicare Parts A and B. For example, exempting female beneficiaries from cost sharing for mammography could encourage better adherence to the U.S. Preventive Services Task Force recommendation that women over 40 get regular screening mammography.⁶⁵

As the Obama Administration and members of Congress explore health reform options, it is important that they not only examine options to increase coverage for the uninsured, but also options to improve quality and contain costs. VBID simultaneously addresses the objectives of cost containment and quality improvement in the delivery of care by promoting “fiscally responsible, clinically sensitive” cost sharing in order to mitigate the well-documented adverse

65 Trivedi A, et al. “Effect of Cost Sharing on Screening Mammography in Medicare Health Plans.” *NEJM* 358, no 4 (2008):375-383.

clinical outcomes associated with the current, one-size-fits-all medical system.⁶⁶ Medicare is an ideal place to implement VBID because beneficiaries are at a much higher risk of adverse events than younger patient populations and ensuring access to necessary care is a fundamental tenet of the Medicare program. VBID is a vital tool that has the potential to transform Medicare into a more prudent purchaser of healthcare services that meet patient needs.

VBID is not a mechanism that will solve our healthcare crisis. Technological advances will continue to generate upward pressure on costs and increasingly strain the ability of individuals and their employers to afford such coverage. That said, compared to the status quo of escalating costs and suboptimal quality of care, the implementation of VBID principles would encourage the use of high-value care and ultimately produce better health outcomes at any level of healthcare expenditure.

66 Fendrick AM, et al. "Value-Based Insurance Design: A 'Clinically Sensitive' Approach to Preserve Quality and Contain Costs." *AJMC* 1 (2006):18-20.

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APPENDIX Recent VBID Studies of Differential Cost Sharing for Chronic Condition Drugs

Article (Lead Author or Publisher, Year)	Description of Intervention	Condition			Use Medicare Data	Outcomes Measured**		
		Diabetes	Hyperten- sion	Other*		Adherence (+/-)	Emergency Medical Use (+/-)	Costs (+/-)
Increased Cost Sharing for Chronic Condition Drugs								
Blustein, 2000	Modeled effect of not having drug coverage on rate at which beneficiaries with hypertension purchased antihypertensive tablets		X		X	-	-	
Chernew, 2008 <i>J Gen Intern Med</i>	Modeled whether doubling copays for medications used to treat diabetes and chronic heart failure decreased adherence at different rates for different income levels	X		X		-	-	
Cole, 2006	Modeled impact of a \$10 increase in copay for beta-blockers and ACEs for chronic heart failure patients			X		-	+	
Gibson, 2006	Modeled impact of across the board copay increases on statin adherence for patients with hypertension		X			-	-	
Goldman, 2004	Modeled impact of doubling copays for eight therapeutic classes on prescription fill rates	X	X	X	X	-	+	
Piette, 2004	Modeled impact of increased copays for diabetes medications on adherence rates	X				-	-	
Roblin, 2005	\$10 increase in copays for oral hypoglycemics	X				-	-	
Decreased Cost Sharing for Chronic Condition Drugs								
Aetna, 2007	ActiveHealth Management reduced copays by \$5 for select generics and by 50 percent for select brands	X	X	X		+		-
Berger, 2007	Pitney Bowes moved all medication for asthma, diabetes, and hypertension to tier 1	X	X	X		+	-	-
Chernew, 2008 <i>Health Aff</i>	ActiveHealth Management reduced copays by \$5 for select generics and by 50 percent for select brands	X	X	X		+		
Choudhry, 2008	Modeled impact of waiving copays for aspirin, beta-blockers, ACEs and ARBs, and statins after acute myocardial infarction			X	X	-	-	-

* Other conditions studied include asthma, rheumatoid arthritis, chronic heart failure, post-acute myocardial infarction, and depression. ** + = increase; - = decrease
 Note: This table is not meant to be a comprehensive review of all studies on differential cost sharing for chronic condition drugs; rather, it seeks to present the more recent studies on this topic.

(Continued)

Article (Lead Author or Publisher, Year)	Description of Intervention	Condition			Use Medicare Data	Outcomes Measured**			
		Diabetes	Hyperten- sion	Other*		Adherence (+/-)	Emergency Medical Use (+/-)	Costs (+/-)	
Decreased Cost Sharing for Chronic Condition Drugs									
Cranor, 2003	Asheville Project—employers waived copays for diabetes medications	X					+	-	-
Drug Benefit News, 2008	M-Healthy—waived or reduced copays of selected medications for University of Michigan faculty, staff and their dependents with diabetes	X					+		
Ellis, 2004	Examined effect of reducing copays of statins on medication adherence among patients with high risk of coronary heart disease			X			+		
Goldman, 2006	Modeled impact of waiving copays for cholesterol-lowering therapy for patients with high cholesterol		X				+	-	-
Greene, 2007	Large employer waived copays for statins for all employees		X				+		-
Mahoney, 2005	Pitney Bowes moved all medication for asthma, diabetes, and hypertension to tier 1	X	X	X			+		
Kamal-Bahl, 2004	Examined impact of incentive-based formularies and anti-hypertensive adherence rates among patients with hypertension		X				+		
Nicholson, 2006	Simulated the effect of moving all diabetes medications to tier 1	X					+		-
Rosen, 2005	Modeled the impact of waiving copays for ACEs for beneficiaries with diabetes	X			X			-	-
Sokol, 2005	Examined the effect of MTMP for patients with diabetes and coronary artery disease	X	X	X	X		+	-	-
Wong, 2001	Examined effect of decreasing copays of select medications for chronic condition patients	X	X	X			+	-	-

* Other conditions studied include asthma, rheumatoid arthritis, chronic heart failure, post-acute myocardial infarction, and depression. ** + = increase; - = decrease
 Note: This table is not meant to be a comprehensive review of all studies on differential cost sharing for chronic condition drugs; rather, it seeks to present the more recent studies on this topic.

