TRENDS FROM THE FIELD

The Redesign of Consumer Cost Sharing for Specialty Drugs at the California Health Insurance Exchange

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hen designed intelligently, cost sharing increases consumer sensitivity to the appropriateness and price of pharmaceutical and medical services, thereby moderating expenditures and rewarding innovations that reduce, rather than increase, the total cost of care. When designed less intelligently, however, cost sharing impedes patient access to beneficial treatments and penalizes effective but expensive innovations.

The US healthcare system is characterized by rising costsharing requirements. High-deductible health plans, defined as insurance products with an annual deductible of at least \$1000 for individual coverage and \$2000 for family coverage, now account for 24% of individuals covered by employment-based health insurance—up from 13% 5 years ago.¹ Of the nearly 10 million individuals participating in US public health insurance exchanges (HIEs) by mid-2015, 22% were enrolled in catastrophic or Bronze-tier plans, in which consumers pay 40% of average healthcare costs.² Over 80% of individuals covered by employment-based insurance now face prescription drug benefits with 3 or 4 tiers, which feature especially high cost sharing.³ Medicare beneficiaries enrolled in Part D plans have seen out-of-pocket spending increase by 31% since 2006.⁴ Additionally, many insurance products subject all specialty drugs to significant cost sharing, thereby limiting the consumer's ability to reduce out-of-pocket expenditures by switching to a less costly brand.⁵

The Affordable Care Act (ACA) mandates that all insurance products cover 10 categories of "essential health benefits" and that cost sharing not exceed a defined maximum per year.⁶ Some states also have legislated limits on cost sharing for particular classes of drugs or other services.⁷ The challenge in reforming health insurance benefits is to limit cost sharing while keeping the overall premiums affordable. This challenge has been especially prominent for HIEs, as they seek to attract low-income and, hence, costconscious, consumers.

ABSTRACT

This paper describes the redesign of health benefits at Covered California—the nation's largest health insurance exchange, which covers 1.3 million individuals, and its benefit designs extending to hundreds of thousands more enrollees through insurance products sold outside the exchange—with respect to specialty drugs for the 2016 enrollment year. The catalyst for benefit redesign came from advocacy organizations representing patients suffering for HIV, multiple sclerosis, epilepsy, hepatitis C, and other chronic conditions.

The first component of the benefit redesign creates a separate deductible for pharmaceutical expenditures, with a commensurate reduction in the deductible for other (medical) expenditures. The second component requires health plans to assign at least 1 specialty drug for each therapeutic class to a nonspecialty tier, offering patients a treatment option for which they are not exposed to coinsurance. The third component imposes a monthly payment limit of \$250 for each specialty drug prescription, thereby buffering patients using these drugs against the \$6250 individual, or \$13,500 family, annual medical payment limit. The pharmacy deductible and monthly out-of-pocket payment limit are substantially lower for low-income enrollees in the subsidized silver-tier products.

The Covered California redesign indicates that patients can be shielded from the most onerous cost-sharing burdens while keeping premiums affordable for the entire enrolled population; however, sustainable access to care requires reductions in the underlying cost of new clinical technologies.

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Take-Away Points

coinsurance.

The California Health Insurance Exchange sought to reduce cost sharing without increasing premiums. Key components included:

- Separate deductible for pharmacy expenditures.
- Requirement that at least 1 specialty drug in each category be exempt from
- Maximum \$250 per month cost sharing on drugs.

Covered California is the nation's largest HIE, covering over 1.3 million individuals in 2015. It has been the most active exchange in designing benefits to protect vulnerable patients while keeping consumer cost sharing within the parameters required by its enabling legislation.⁸ This paper describes Covered California's benefit redesign with respect to specialty drugs for the 2016 enrollment year. It highlights both the gains in patient protection that can be obtained through an active benefit-design strategy, as well as the limits to what any purchaser can achieve unless the healthcare sector can attain broader efficiencies.

The Problem: Poorly Designed Insurance

Poorly designed consumer cost sharing in health insurance creates several important problems. It not only imposes excessive barriers to accessing effective care, especially for the sickest patients and those with low incomes, but it also reduces the use of effective, as well as ineffective, treatments. The financial burden undermines adherence to physician prescriptions, leading to adverse health outcomes for some patients.

Payment for the services reimbursed by health insurance is divided between the insurance premium—which is paid by all enrollees regardless of health status—and the cost-sharing provisions, which are disproportionately borne by the sickest enrollees who utilize the most care. Patients generally must satisfy an annual deductible, which may require as much as \$5000 in out-of-pocket payment before the insurer begins to help cover costs. Many plans impose coinsurance, where patients pay a percentage of the insurer's contracted fee; subsequently, the patient's financial responsibility rises proportionally to the cost of the services used for expenses incurred after the annual deductible has been met.

For insurance products purchased outside of HIEs, cost sharing typically is not adjusted for income and, therefore, is a more serious burden for low-income than for high-income patients. The financial impact of cost sharing is also much greater for patients suffering from serious medical conditions than for their healthier compatriots. This blow to a patient's finances can wreak havoc on their life; for example, before implementation of the ACA, patients with cancer were 2.65 times more likely than individuals not suffering from the condition to file for personal bankruptcy.⁹

Additionally, high cost sharing reduces patient adherence to drug prescriptions, and thereby lowers the prognosis of pa-

tients suffering from treatable conditions. Reductions in adherence have been documented most extensively for drugs used in the treatment of chronic conditions, such as coronary artery disease, hypertension, diabetes, and chronic obstructive pulmonary disease.¹⁰⁻¹² Cost sharing has also been found to reduce utilization of specialty drugs, a matter of particular concern given the severity of the underlying disease states being treated. For example, research on use of biologics for rheumatoid arthritis found that doubling the average out-of-pocket costs reduces the predicted probability of initiating use by 9.3% and the predicted probability of continuing use by 3.8%.¹³

Cost sharing is not adjusted for the clinical value of the treatment and does not differentiate between appropriate (eg, prescriptions that are consistent with the FDA label) versus inappropriate uses of a drug. Therefore, it does not send a signal to physicians to prescribe using evidence-based criteria, and to innovators to develop truly novel and effective drugs.¹⁴

Health Insurance Exchanges

The ACA mandated the creation of federal and state HIEs to facilitate the purchasing of coverage by individuals not eligible for employment-based, or publicly provided, insurance. The legislation specifies several important components of the products that may be offered, but leaves considerable discretion to exchange administrators with respect to deductibles, coinsurance, and other cost-sharing features. Exchange administrators have particularly wide latitude in designing cost sharing for drugs, reflecting the traditional segmentation between medical and pharmacy benefits in employment-based insurance.

Under the terms of the ACA, health insurance plans offered through a public HIE must cover 10 categories of "essential health benefits," such as physician services, hospital care, and pharmaceuticals. All insurance products must meet or exceed the benefits specified by a benchmark product that is selected by each exchange as a point of reference. All products sold on the exchange must have an actuarial value (AV) that does not exceed defined percentages for premiums and cost sharing. Insurance products are grouped into 4 "metal" tiers, according to whether their AV is 60% (Bronze), 70% (Silver), 80% (Gold), or 90% (Platinum). The AV percentage reflects the tradeoff between premiums and cost-sharing requirements. Bronze plans have the lowest premiums and highest cost-sharing requirements, whereas Platinum plans feature the lowest cost sharing but highest premiums. The ACA imposes an out-of-pocket payment maximum for all covered services, which increases each year based on the rate of growth in healthcare costs.

Metal tier assignments impose discipline on the costsharing requirements. On the one hand, overly generous coverage forces a product into the high-premium Gold or Platinum tiers, which attract only small numbers of enrollees. On the other hand, insufficiently generous coverage imposes onerous financial costs on the most vulnerable members of society.¹⁵ Grouping insurance products by metal tier facilitates informed shopping by consumers, who are better able to compare out-of-pocket costs with the premium for each product option.

HIE enrollees whose household income falls below 400% of the federal poverty level are eligible for subsidies that help cover the premiums. Enrollees with income under 250% of the federal poverty level are eligible for supplemental subsidies that also offset cost sharing. Enrollees who are eligible for cost-sharing subsidies receive them only if they choose Silver-tier products. States have further defined subsidized sub-tiers within the Silver category, called "enhanced Silver plans," with AVs of 73%, 87%, and 94% of the benchmark plan. Enrollees selecting these subsidized plans incur significantly less cost sharing than nonsubsidized enrollees selecting Silver plans, and sometimes less than nonsubsidized enrollees selecting Gold and Platinum plans.

Covered California

The legislated structure of an HIE permits significant cost sharing for specialty drugs. High cost sharing reduces the payments that the health insurance plan itself needs to make, allowing it to charge lower premiums and thereby grow its market share. Health insurers may institute high cost-sharing requirements for strategic purposes, as these requirements discourage enrollment by consumers suffering from serious conditions. The HIE seeks to adjust premiums for the risk mix of each insurer's enrollees, but these adjustments may not adequately compensate for the cost of specialty drugs.

With over 1.3 million enrollees in 2015, Covered California is the largest HIE in the nation and is also the most active in terms of its purchasing strategy.¹⁶ It does not leave the definition of benefit coverage and cost sharing to the health plans; on the contrary, it specifies the details of deductibles, coinsurance, out-of-pocket maximums, and other design features. It dictates a cost-sharing structure for each of the 4 metal tiers, including each of the subsidized Silver sub-tiers. Health insurance companies in California also must offer these benefit designs in the off-exchange market. The HIE's design, therefore, affects hundreds of thousands of enrollees in these off-exchange insurance products, over and above the 1.3 million enrollees in Covered California.

Although it has considerable discretion in designing benefits, Covered California must ensure that the AV of each product does not exceed the legislated level for each metal tier; therefore, it is not possible to drastically limit cost sharing for specialty drugs. In 2015, very few Covered California enrollees selected the most generous product designs (ie, Platinum or Gold). As highlighted in

	Product and Actuarial Value						
	Bronze (60%)	Silver (70%)	Enhanced Silver (73%)	Enhanced Silver (87%)	Enhanced Silver (94%)	Gold (80%)	Platinum (90%)
Number of enrollees (as of 2015)	325,870	172,650	126,640	348,730	197,360	68,950	59,440
Specialty drug coinsurance	100%	20%	20%	15%	10%	20%	10%
Drug monthly maximum	\$500	\$250	\$250	\$150	\$150	\$250	\$250
Individual: pharmacy deductible	\$500	\$250	\$250	\$50	\$0	\$0	\$0
Individual: medical deductible	\$6000	\$2250	\$1900	\$550	\$75	\$0	\$0
Individual: annual maximum	\$6500	\$6250	\$5450	\$2250	\$2250	\$6200	\$4000
Family: pharmacy deductible	\$1000	\$500	\$250	\$50	\$0	\$0	\$0
Family: medical deductible	\$12,000	\$4500	\$3800	\$1100	\$150	\$0	\$0
Family: annual maximum	\$13,000	\$12,500	\$10,900	\$4500	\$4500	\$12,400	\$8000

Table. 2016 Pharmaceutical Cost Sharing for Enrollees in Covered California, by Type of Insurance Product

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the **Table**, these 2 top-tier products each attracted only 5% of total enrollment. The majority selected Silver (65% of enrollees) and Bronze (25% of enrollees) products. Of those selecting Silver products, 80% were eligible for cost-sharing subsidies through the enhanced Silver products. Together, the 3 subsidized Silver products attracted 51% of total enrollment.¹⁷

Benefit Design for Specialty Drugs

The catalyst for specialty drug benefit redesign at Covered California came from advocacy organizations representing patients suffering from HIV, multiple sclerosis, epilepsy, hepatitis C, and other chronic conditions where the standard of care includes the use of specialty drugs. In 2015, Covered California formed a workgroup of agency staff, patient advocates, and representatives of participating health plans to provide input on benefit redesign for the 2016 plan year. The principal focus was on increased financial protection and access to high-cost drugs. Design changes were made to the pharmacy deductible, the ability for insurers to assign all high-cost drugs to the specialty drug tier, and the cost-sharing limit. The Table presents the pharmaceutical cost-sharing requirements for individuals and families selecting each of the 4 standard and 3 enhanced plans at Covered California for 2016.

Prior to the benefit redesign, the Bronze and Silver plans had required that enrollees meet their medical deductible before receiving any financial support for specialty drugs. This was particularly important for enrollees in the Bronze plans, which featured a deductible of \$6250. Enrollees in the Silver plan faced deductibles of \$2250 unless they were eligible for one of the subsidized cost-sharing plans.

The first component of the benefit redesign was to create a separate deductible for pharmaceutical expenditures, with a commensurate reduction in the deductible for other (medical) expenditures. Now a patient would only need to meet a much more modest deductible before receiving some financial protection for specialty drugs. As illustrated in the Table, the pharmacy deductible was established at \$250 for the most commonly selected products (the Silver tier), with reductions off that level for low-income patients eligible for federal subsidies. For Bronze plans, the pharmacy deductible was set at \$500 in order to keep the AV of those products in line with the 60% requirement.

Covered California imposes dollar co-payment and percentage coinsurance requirements that patients must pay after meeting their deductibles. Prior to the benefit redesign, requirements for nonspecialty drugs were expressed in terms of dollar co-payments, such as \$15 for generics, \$50 for preferred brands, and \$70 for nonpreferred brands. In contrast, cost-sharing requirements for specialty drugs were expressed as percentage coinsurance, including 20% in the standard Silver plan.

Coinsurance constituted the greatest financial risk for patients suffering from severe medical conditions. Many patients had no ability to limit their financial exposure since their health plan had assigned all the drugs for their condition to the coinsurance-based specialty tier. As part of the redesign, health plans must now assign at least 1 specialty drug for each therapeutic class to a nonspecialty tier. This offers to patients at least 1 treatment option for which they are not exposed to coinsurance. This requirement was limited to therapeutic classes where there existed 3 or more specialty drugs.¹⁸

The use of coinsurance for specialty drugs also focused the workgroup's attention on the maximum out-of-pocket payment limits. The ACA had established an annual maximum for 2016 of \$6850 for individual coverage and \$13,700 for families. Covered California had set the maximum lower at \$6500 for individuals and \$13,000 for families. Without additional protections, patients needing specialty drugs could be required to pay this amount, even after satisfying their pharmaceutical deductible. As part of the benefit redesign, Covered California implemented a monthly payment limit of \$250 for each specialty drug prescription. Going forward, a patient who is responsible for 20% coinsurance will only pay \$250 per month (after having met the pharmacy deductible), even if the monthly price of the drug is \$2000 or more. Patients eligible for cost-sharing reduction plans will face lower per-prescription maximums. Patients selecting the Bronze plan, however, will be required to pay up to \$500 per prescription per month, in addition to meeting a \$500 pharmacy deductible.

In addition to structuring the standardized benefit design to increase financial protection, Covered California instituted requirements on the participating health insurers that would increase the ability of enrollees to understand their coverage options. The workgroup agreed to a standard definition of which classes of drugs could be assigned to each of the 4 formulary tiers (generic, preferred brand, nonpreferred brand, and specialty). Individual plans retain the right to assign particular drugs to particular tiers or to exclude them from the formulary altogether, but they will need to clearly indicate which drugs are in which tier, maintain a dedicated pharmacy customer service line, clearly message the plan's exception policy for patients needing drugs not on the approved formulary, and provide an estimate to enrollees of their out-of-pocket obligations for each drug.

Conclusions

Despite improvements in financial protection for patients using specialty drugs, insurance design efforts are vulnerable to escalation in the underlying cost of health services. As pharmaceutical firms launch effective but expensive new products, health plans either must raise their premiums, increase consumer cost sharing, or both. The Covered California staff has discussed additional protections for patients using specialty drugs, but they fear that cost sharing may need to increase, not decrease, in light of the continuous escalation in specialty drug prices. After almost a decade of stability, national prescription drug spending grew by 12.6% in 2014, and CMS expects outpatient prescription drug spending to grow at annual rates of 6% or more in the coming years.¹⁹ Premiums now must incorporate the cost of new drugs for hepatitis C, coronary artery disease, cancer, and other prevalent conditions. Over the long term, patient access to effective care will only be guaranteed if the health system finds a way to stimulate innovations that decrease, rather than increase, the total cost of care.

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