

State Health Reform Assistance Network

Charting the Road to Coverage

ISSUE BRIEF

August 2014

Specialty Tier Pharmacy Benefit Designs in Commercial Insurance Policies: Issues and Considerations

Prepared by **Sally McCarty** and **David Cusano**, Center on Health Insurance Reforms, Georgetown Health Policy Institute

Overview

As health care costs increase, one of the chief determinants of the rate of increase has been the cost of prescription drugs. The role of prescription drugs in the overall medical Consumer Price Index (CPI) is clearly illustrated by the Bureau of Labor Statistics' CPI report for June 2014. The Bureau reported a 2.6 percent growth rate for the medical services CPI, and a 2.8 percent growth rate for the medical commodities CPI between June 2013 and June 2014.¹ Yet, prescription drugs, a component of the medical commodities index, increased by 4.1 percent during the same period.² And that growth is expected to continue. In their 2013 Drug Trend Report, Express Scripts predicts that the cost of traditional (nonspecialty) drugs will increase at a rate of 2 percent each year for the next three years while, during the same period, the report predicts the cost of specialty drugs will increase at eight times that rate, or 16 percent per year. The report attributes the growth to expensive new therapies and "expanding indications for existing drugs."³

Over the past 20 years, health insurers have experimented with different approaches to moderating the costs of providing prescription drug coverage to their enrollees. The one design that has survived and emerged as the most common approach is the tiering of benefits, or benefit designs that assign covered prescription drugs to a "tier" based on cost-sharing and other requirements, like preauthorization. Early tiered pharmacy benefits were generally simple, two-tiered designs with generic drugs on the first tier and brand name drugs on the second tier. The next iteration included three tiers; with the brand name (second) tier becoming two tiers: brand name drugs with generic equivalents and brand name drugs with no generic equivalents. Those with generic equivalents were assigned to the third tier with more cost-sharing and restrictions. Another version of the three-tier design divided the second tier into a tier for preferred brand name drugs and a third tier for nonpreferred brand name drugs.

Over time, additional tiers have been added to pharmacy benefit designs and, as they were added, cost-sharing in the new, higher tiers has increased. With the enactment of the Affordable Care Act (ACA), which eliminated underwriting and imposed the federal minimum loss ratio, or MLR (a limit on administrative and

ABOUT STATE NETWORK

State Health Reform Assistance Network, a program of the Robert Wood Johnson Foundation, provides in-depth technical support to states to maximize coverage gains as they implement key provisions of the Affordable Care Act. The program is managed by the Woodrow Wilson School of Public and International Affairs at Princeton University. For more information, visit www.statenetwork.org.

ABOUT GEORGETOWN UNIVERSITY'S CENTER ON HEALTH INSURANCE REFORMS

Georgetown University's Center on Health Insurance Reforms (CHIR) is composed of a team of nationally recognized experts on private health insurance and health reform. The Center is based at Georgetown University's Health Policy Institute (HPI), and works regularly with a multidisciplinary group of faculty and staff dedicated to conducting research on issues related to health policy and health services. HPI is affiliated with the University's public policy graduate programs (the *McCourt School of Public Policy*). For more information on Georgetown's CHIR, visit chir.georgetown.edu.

ABOUT THE ROBERT WOOD JOHNSON FOUNDATION

For more than 40 years the Robert Wood Johnson Foundation has worked to improve the health and health care of all Americans. We are striving to build a national culture of health that will enable all Americans to live longer, healthier lives now and for generations to come. For more information, visit www.rwjf.org. Follow the Foundation on Twitter at www.rwjf.org/twitter or on Facebook at www.rwjf.org/facebook.

For more information, please contact Sally McCarty at sally.mccarty@georgetown.edu or 202.557.8344.

¹ Bureau of Labor Statistics, U.S. Department of Labor, Consumer Price Index, June 2014, pg. 9.

² Id. at 13.

³ The Express Scripts 2013 Drug Trend Report, April 2014, pg. 5.



other non-health care spending), health insurers have looked to pharmacy benefit designs as one of the few remaining mechanisms for controlling costs. As a result, tiered pharmacy benefit designs with as many as five or six tiers are emerging. Consequently, for those in need of drugs on the higher tiers with the most cost-sharing, three important issues have emerged for regulators to consider: 1) the affordability of prescription drug therapies for those who need them most; 2) the adherence challenges that result from loss of affordability; and 3) the potential for tiered pharmacy benefit designs to violate the anti-discrimination provisions of the ACA. This issue brief will explore those issues and offer potential regulatory approaches to address them.

Background

Individuals with chronic, rare, or other serious diseases and the advocacy groups that represent them became concerned when, in the early 2000s, simpler versions of two or three-tiered pharmaceutical benefit designs started sprouting fourth tiers accompanied by additional cost-sharing and authorization requirements (like step therapy⁴ or preauthorization). “Specialty drugs,” the drugs necessary to the health or even survival of those individuals, were commonly assigned to the fourth tier and, during that period, began to be referred to as “tier four drugs.” A comprehensive definition of specialty drug used in some state statutes and legislation is a drug that:

1. Is prescribed for an individual with a:
 - a. Complex or chronic medical condition, or
 - b. Rare medical condition
2. Costs \$600 or more for up to a 30-day supply
3. Is not typically stocked at retail pharmacies
4. Requires either:
 - a. A difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug; or
 - b. Enhanced patient education, management, or support beyond those required for traditional dispensing before or after administration of the drug.⁵

Because the fourth or higher tiers were created to cull out specialty drugs and include the most burdensome requirements, they have become known as “specialty tiers.”

Cost issues

Since the advent of tier four drugs, there has been a growing concern (which continues today) among chronically and seriously ill individuals and their advocates about the increasing patient share of the cost of vitally needed specialty tier drugs. As more tiers are added to prescription drug benefit designs, those individuals have seen their medications move up the tier structure (current plans may have as many as five or six tiers) and with each move up comes a concomitant increase in cost to the patient and, in many instances, additional requirements that must be met to secure authorization for coverage. These changes make affordability of drug therapies for the seriously and chronically ill increasingly elusive.

A reliable resource for tracing the development of specialty tiers in health insurance plans is the Kaiser Family Foundation’s annual Employer Health Benefits Survey. The survey first began reporting information about a fourth tier in employer prescription drug benefit designs in 2004.⁶ That survey report described designs with a fourth tier as “new types of cost-sharing arrangements that typically build additional layers of higher co-payments or co-insurance for specifically identified types of drugs, such as lifestyle or injectable drugs.”⁷ At that time, 3 percent of the covered employees of survey respondents were in plans that included a four-tier pharmacy benefit design. In 2008, the survey question was altered to ask if the benefit design included four *or more* tiers. That year’s survey report showed that 7 percent of employees of responding employers were covered by plans with pharmacy benefits that included four or more tiers.⁸

In the 2013 survey report, the most recent year available, 23 percent of covered employees were in plans using pharmacy benefit designs with four or more tiers, nearly 800 percent more than in 2004 when the four-tier question was first asked. During that same

⁴ Step therapy is a pharmacy benefit design that requires the trial use of a similar, less expensive drug to assess its effectiveness before a more expensive drug will be authorized.

⁵ This definition appears in Maryland Insurance Article §15-847 and Virginia HB 304.

⁶ Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits Survey, 2004, pg. 114.

⁷ Id. at 115.

⁸ Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits Survey, 2008, pg. 142.

period, the percentage of employees covered by a three-tier pharmaceutical benefit design dropped from 65 percent to 59 percent, and the percentage of employees in two-tiered plans was halved, dropping from 20 percent in 2004 to 10 percent in 2013.⁹

Additionally, the 2013 annual Kaiser Employer Survey report indicates that between 2004 and 2013, the average co-payment for generic drugs in plans with three or more tiers fluctuated between \$10 and \$11 and was \$11 in 2013. During the same period, the average co-payment for tier four or higher drugs also fluctuated, with a low of \$59 in 2004 and a high of \$91 in 2011. The 2013 average co-payment for tier four drugs was \$80, almost eight times the average co-payment for a generic drug.¹⁰ The report also indicated that 48 percent of employees in plans with four or more tiers are paying co-insurance as opposed to 39 percent who are paying co-payments.¹¹

Adherence issues

In addition to cost concerns, the indirect correlation between treatment cost and patient adherence to drug therapy regimens can present serious consequences for the health status of individuals dependent on specialty drugs. A group of University of North Carolina researchers studied more than 1,500 patients with chronic myeloid leukemia (CML) and their adherence to a tyrosine kinase inhibitor (TKI), a treatment that has greatly increased survival rates for CML patients. The report of their study was published in the December 2013 issue of the *Journal of Clinical Oncology*. It concluded that nonadherence to TKI therapy “undoubtedly results in disease progression and treatment resistance,” and when the cost to the patient becomes too high, many will skip doses or stop the drug completely. More specifically, patients with higher co-payments were 70 percent more likely to stop their medication, and were 42 percent more likely to skip doses than patients with low co-payments.¹²

In the January 2012 edition of *P & T: A Peer Reviewed Journal for Formulary Management*, researchers reported on a literature review of 160 abstracts and articles using the following search terms: adherence, compliance, co-pay, cost-sharing, costs, noncompliance, outcomes, hospitalization, utilization, economics, income, and persistence. The articles reviewed covered a wide variety of interventions, measures, and populations, but, even with the variation, the researchers were able to identify “relatively clear relationships between cost-sharing, adherence, and outcomes.” They found that 85 percent of the articles evaluating the relationship between changes in cost-sharing and adherence showed that an increasing patient share of medication costs was significantly associated with a decrease in adherence.¹³

Both studies present cause for concern because they point out the potential danger posed by specialty tier benefit designs to individuals reliant on specialty drugs. As the use of these designs increases, and affordability and access are reduced by additional cost-sharing and authorization requirements, the health of the most seriously ill can be placed in grave jeopardy.

Specialty tiers and ACA nondiscrimination

A third significant concern is that formulary designs with four or more tiers may implicate the new nondiscrimination protections under the ACA if an insurer is using these designs to intentionally shift the cost of expensive prescription drugs to individuals with specific diseases. Specifically, Section 1557 of the ACA extends existing federal civil rights protections to private health insurance and prohibits individuals from being subject to discrimination, excluded from participation, or denied the benefits of health programs or activities based on race, color, national origin, sex, age, or disability.¹⁴

The Office of Civil Rights (OCR) within the Department of Health and Human Services (HHS) has jurisdiction and enforcement authority over this provision. In fact, the AIDS Institute and National Health Law Program recently filed a complaint with OCR against four insurers (Coventry One, Cigna, Humana, and Preferred Medical) claiming discrimination under Section 1557 of the ACA.¹⁵ The complaint alleges that the qualified health plans offered by these insurers on the Florida Marketplace impose overly restrictive utilization management requirements on HIV/AIDS medications and places all HIV/AIDS medications on the highest

⁹ Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits Survey, 2013*, pg. 150.

¹⁰ *Id.* at 153.

¹¹ *Id.* at 148.

¹² Dusetzina SB, Winn AN, Abel GA, et al. Cost-sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. *Journal of Clinical Oncology*. 2014; 32:306–311.

¹³ Eaddy MT, Cook CL, O'Day K, Burch SP, Cantrell CR. How patient cost-sharing trends affect adherence and outcomes: a literature review. *P & T: A Peer Reviewed Journal for Formulary Management*. 2012; 37(1):45–55.

¹⁴ 42 U.S.C. § 18116 (2012).

¹⁵ Administrative Complaint, *AIDS Institute v. Coventry Health Care, Inc.*, Office of Civil Rights, U.S. Department of Health and Human Services, May 29, 2014.

cost-sharing tier, thus discouraging individuals diagnosed with HIV and AIDS from enrolling in these plans.¹⁶ Advocates in Georgia are planning to file a similar complaint with the OCR.¹⁷

Additionally, insurers offering coverage in the individual and small group markets in a state both within or outside of the marketplace are required to offer the ten categories of essential health benefits (EHB) as set forth in that state's benchmark plan.¹⁸ Insurers do not comply with this requirement if their benefit plan designs discriminate against an individual based on age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.¹⁹ Insurers offering EHB in the individual and small group markets also are prohibited from implementing plan designs that discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, sexual orientation, or significant health needs.²⁰ The states and HHS have jurisdiction and enforcement authority over these provisions.

State legislative initiatives

Several states have introduced legislation that limits cost-sharing for specialty drugs (see Appendix A on page 6). The most common legislative initiatives include a cap of \$150 for a 30-day supply of a single specialty tier drug. Delaware, Louisiana, and Maryland have enacted laws that include that provision. Delaware and Louisiana laws also include a requirement that issuers who utilize a specialty drug formulary establish an appeals process for enrollees whose health care providers attest that a nonformulary drug would be the most effective treatment for their disease or condition. Virginia and Hawaii have introduced legislation with the same two provisions. Additionally, each of those two states' initiatives, as well as Delaware's law, prohibits issuers from placing all drugs of a particular class on a specialty tier. Maryland's new law requires the \$150 cap to be revisited each year and adjusted based on the medical care Consumer Price Index.

Illinois legislators introduced a House bill in February 2014 and a companion Senate bill three months later. Both bills seek to limit cost-sharing for specialty tier drugs to \$100 for a single drug and \$200 in the aggregate per 30-day period. Both also include the provision requiring issuers to establish an appeal process for nonformulary drugs. An additional provision in the House bill would limit annual out-of-pocket cost-sharing for prescription drugs to 50 percent of the federal out-of-pocket limits, both for self and for family.

Legislative initiatives introduced in California, Mississippi, and New York include different provisions than those in other states. California's bill limits cost-sharing for a 30-day supply of drugs that do not have a time-limited course of treatment, or have a course of treatment that lasts more than three months, to one-twelfth of the annual out-of-pocket limit applicable to self-only coverage. If a product has a course of treatment that lasts less than three months, the total cost-sharing cannot exceed half of the of the annual out-of-pocket limit.

New York's initiative instructs the Superintendent of Insurance to deny policies imposing drug tiers based on expense or disease category and that charge a cost-sharing percentage (co-insurance) for prescription medication. The bill also prohibits the issuance of policies that categorize prescription drugs based on a specific disease or specific cost and that charge based on a cost-sharing percentage.

Mississippi's initiative, which failed to progress out of committee in February 2014, also prohibited the creation of specialty tiers that utilize co-insurance as a cost-sharing measure and limited co-payments to 500 percent of the lowest co-payment for a drug on the policy formulary. The bill also capped out-of-pocket expenses for prescription drugs at \$1,000 per contract year per insured individual, or \$2,000 per contract year per insured family, adjusted for inflation. Additionally, the Mississippi initiative required any out-of-pocket limit for prescription drugs to be included in the out-of-pocket maximum amount for all services under the contract.

Federal legislation

The only federal legislative initiative to be introduced to date is the Patients' Access to Treatment Act of 2013 (H.R. 460), introduced by West Virginia Representative David B. McKinley on February 4, 2014. H.R. 460 seeks to establish cost-sharing limits for health plans that cover prescription drugs and use a formulary or other tiered cost-sharing structure; and prohibits cost-sharing in a specialty drug tier that exceeds the dollar amount of cost-sharing for the lowest cost, nonpreferred drug tier. The bill was referred to the House Subcommittee on Health on February 8, 2014 and has seen no action since that date.

¹⁶ Id.

¹⁷ Associated Press, "AIDS Patients Fear Discrimination in ACA Exchange," *Washington Post*, August 6, 2014.

¹⁸ 45 C.F.R. §§ 147.150 & 156.115.

¹⁹ 45 C.F.R. § 156.125.

²⁰ See 45 C.F.R. §§ 147.104(e), 156.200(e) & 156.225.

Going forward

The challenges presented by the growing number of pharmacy benefit designs using specialty tiers are significant. As with so many health insurance issues, states have addressed the problems arising from specialty tier benefit designs in a variety of ways, creating a patchwork of activity ranging from strong statutory solutions that address affordability issues to no attention paid to the issue at all. Those states that have attempted to address or have succeeded in addressing the challenges have several approaches in common (see Appendix B on page 8).

To address cost concerns, the most effective solution would be the one that three states have adopted, and additional states are attempting to enact, namely, caps on out-of-pocket expenses for specialty tier drugs and a process for enrollees needing nonformulary drugs to seek an exception.

The proposed federal legislation, which ties cost-sharing for specialty tier drugs to the dollar amount of cost-sharing for the lowest nonpreferred drug tier, would provide a suitable federal floor for states to adhere to or build upon. And, some of the stronger provisions that have been introduced in state legislatures, like prohibiting co-insurance as cost-sharing for specialty tier drugs and prohibiting the placement of all drugs of the same class on a specialty tier, would go a long way in making specialty tier drugs more affordable for those who need them most.

The problems with adherence to potentially lifesaving drug therapies would most likely be substantially ameliorated if affordability of specialty tier drugs can be achieved. Still, health insurers should reconsider the cost versus value of requirements like prior authorization for specialty drug prescriptions. Apart from the risk to adherence posed by placing such obstacles between patient and treatment, the average primary care office spends roughly 15 hours per week interacting with health insurers about prescription drug issues, time that could be better spent devoted to patient care.²¹ Promoting and supporting adherence is crucial not only (and primarily) for the health of the individuals whose conditions require the drug therapies, but also to preventing more serious illness and costs that may occur when adherence is not achieved.

Finally, potential for discrimination against groups of individuals with diseases and conditions that require costly prescription drugs may be quite real with pharmacy benefit designs that include specialty tiers. While state insurance regulators do not always have the staff or other resources to detect discriminatory designs during the form review process, advocates and other supportive groups may be able to offer assistance by promoting legislative efforts and developing new and creative resources to examine tiered formularies with specific groups or conditions in mind, much like the analysis conducted by the groups that filed the complaint against the Florida insurers.

The issues presented by specialty tier benefit designs in health insurance plans can best be addressed by the combined efforts of state and federal legislators, insurance regulators, advocates, and other interested groups. With the emergence of new and increasingly more expensive specialty drugs, those efforts should focus on ensuring the implementation of pharmacy benefit designs that make specialty tier drugs affordable, improve adherence, and eliminate discriminatory designs.

²¹ Casalino LP, Nicolson S, Gans DN, et al. What does it cost physician practices to interact with health insurance plans? *Health Affairs*. July/August 2009; 28.4: 533-543.

Appendix A

SPECIALTY TIER LEGISLATION ENACTED, EFFECTIVE, OR OTHER ACTION IN 2014

STATE	BILL/LAW	INTRODUCED/ ENACTED	SUMMARY OF PROVISIONS	LAST ACTION
California	AB 1917	Introduced 2/19/2014	<ul style="list-style-type: none"> For drugs used in a course of treatment with no time limit or that lasts longer than three months: Cost-sharing for a 30-day supply cannot exceed 1/12 of the annual out-of-pocket limit applicable to self-only coverage. For drugs used in a course of treatment that lasts less than three months: Cost-sharing cannot exceed ½ of the annual out-of-pocket limit applicable for self-only coverage. 	Passed Senate on 6/26/2014 and referred to Committee on Appropriations for Hearing scheduled for 8/4/2014
Delaware	18 Del. Laws. C. 33, §3364	Enacted 7/23/2013	<ul style="list-style-type: none"> Limits co-payment or co-insurance for specialty tier drugs to \$150 for a 30-day supply of any single specialty tier drug. Requires issuers with a specialty drug formulary to implement a process for enrollees to seek exceptions. Prohibits issuers from placing all drugs of a particular class on the specialty tier. 	Effective 1/1/2014
Hawaii	SB 2173	Introduced 1/16/2014	<ul style="list-style-type: none"> Limits co-payment or co-insurance for specialty tier drugs to \$150 for a 30-day supply of any single specialty tier drug. Requires issuers with a specialty drug formulary to implement a process for enrollees to seek exceptions. Prohibits issuers from placing all drugs of a particular class on the specialty tier. 	Deferred by the Senate Committee on Health 2/14/2014
Illinois	HB 6277	Introduced 5/27/2014 (companion to SB 3395)	<ul style="list-style-type: none"> Limits co-payments or co-insurance for a specialty tier drug to \$100 and \$200 in the aggregate for a 30-day period before or after any applicable deductible is met. Annual out-of-pocket limits for prescription drugs are limited to 50% of the federal out-of-pocket limits for self and family. Requires issuers with a specialty drug formulary to implement a process for enrollees to seek exceptions. 	Referred to Rules Committee 5/27/2014
	SB 3395	Introduced 2/14/2014	<ul style="list-style-type: none"> Limits co-payments or co-insurance for a specialty tier drug to \$100 and \$200 in the aggregate for a 30-day period. Requires issuers with a specialty drug formulary to implement a process for enrollees to seek exceptions. 	Re-referred to Assignments 3/28/2014
Louisiana	HEA 453	Enacted 6/4/2014	<ul style="list-style-type: none"> Limits co-payment or co-insurance for specialty tier drugs to \$150 for a 30-day supply of any single specialty tier drug—<i>after</i> any deductible and <i>until</i> maximum out-of-pocket amount is reached. Requires issuers with a specialty drug formulary to implement a process for enrollees to seek exception. 	Adds R.S. 22:1060.5 to the insurance code. Effective 1/1/2015
Maryland	Insurance Article §15-847	Enacted 5/5/2014	<ul style="list-style-type: none"> Limits co-payment or co-insurance for specialty tier drugs to \$150 for a 30-day supply of any single specialty tier drug. Any increase in limit will occur on July 1 of each year and will be indexed to the medical care component of the March CPI. 	Effective 10/1/2014

STATE	BILL/LAW	INTRODUCED/ ENACTED	SUMMARY OF PROVISIONS	LAST ACTION
Mississippi	HB 1050	Introduced 1/20/2014	<ul style="list-style-type: none"> • Prohibits the creation of specialty tiers that require payment of a percentage of the cost of prescription drugs. • Co-payments limited to 500% of lowest co-payment for a drug on the policy's formulary. • Out-of-pocket expenses for prescription drugs must be included in the out-of-pocket maximum for all services under the contract. • Out-of-pocket expenses for prescription drugs may not exceed \$1,000 per contract year per insured individual or \$2,000 per contract year per insured family—adjusted for inflation. • An issuer must provide 60-days written notice to all affected enrollees before a formulary modification takes effect. 	Died in Committee 2/4/2014
New York	A 2655	Introduced 1/17/2013	<ul style="list-style-type: none"> • Instructs the Superintendent of Insurance to deny policies imposing drug tiers based on expense or disease category. • Policies may not charge based on a cost-sharing percentage. 	Referred to Insurance Committee 1/8/2014
Virginia	HB 304	Introduced 12/31/2013	<ul style="list-style-type: none"> • Limits co-payment and co-insurance for specialty tier drugs to \$150 for a 30-day supply of any single specialty tier drug. • Requires issuers with a specialty drug formulary to implement a process for enrollees to seek exceptions. • Prohibits issuers from placing all drugs of a particular class on the specialty tier. 	Left in Commerce and Labor Committee 2/12/2014
Federal Legislation	H.R. 460 Patients' Access to Treatments Act of 2013	Introduced 2/4/2014	<ul style="list-style-type: none"> • Establishes cost-sharing limits for health plans that use a formulary or other tiered pharmacy benefit cost-sharing structure. • Prohibits cost-sharing in a specialty drug tier that exceeds the cost-sharing dollar amount of in the lowest cost, nonpreferred tier. 	Referred to House Subcommittee on Health 2/8/2014

Appendix B

MOST COMMON PROVISIONS AMONG STATE AND FEDERAL LEGISLATIVE INITIATIVES

STATE	CAP OR LIMIT ON COST-SHARING	APPEAL PROCESS FOR NONFORMULARY DRUGS	PROHIBITIONS		
			ALL DRUGS OF SAME CLASS ON SPECIALTY TIERS	CO-INSURANCE FOR SPECIALTY TIER DRUGS	DRUG TIERS BASED ON EXPENSE OR DISEASE CATEGORY
California	X				
Delaware	X	X	X		
Hawaii	X	X	X		
Illinois	X	X			
Louisiana	X	X			
Maryland	X				
Mississippi	X			X	
New York	X			X	X
Federal	X				