Cost Sharing and Specialty Tier Pricing of Prescription Medications

Joint Commission on Health Care
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Purpose of Study

- 2011: HJR 579 (Delegate O'Bannon) directed the Joint Commission on Health Care (JCHC) to conduct a 2 year study to:
  - Determine the impact of cost sharing, coinsurance and specialty tier pricing on access to prescription medications for chronic health disorders, and
  - Identify and evaluate options for reducing any negative impacts of cost sharing, coinsurance and specialty tier pricing, including but not limited to statutory limitations on cost sharing obligations for prescription medications
- Left in House Rules Committee, but agreed to by JCHC members
- A public meeting was held on May 30, 2012 to receive input from key stakeholders including the National Federation of Independent Business, National MS Society, Patient Advocate Foundation, UCB Pharmaceuticals, U.S. Pain Foundation, Virginia Association of Health Plans, Virginia Chamber of Commerce, Virginia Hemophilia Foundation, Virginia Pharmacists Association, and citizens affected by specialty tier pricing

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Abbreviations

- Abbreviations used in Tables in this presentation include:
  - HDHP/SO – High Deductible Health Plan with Savings Option
  - HMO – Health Maintenance Organization
  - OOP – Out-of-Pocket
  - POS – Point of Service
  - PPO – Preferred Provider Organization

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Cost Sharing Tiers for Prescription Medications

- In the U.S., 88% of covered workers have a tiered cost-sharing formula for prescription drugs[1]
- Cost-sharing tiers for drug formularies:
  - Tier 1: Generic
  - Tier 2: Preferred Brand
  - Tier 3: Non-Preferred Brand
  - Tier 4: Specialty Drugs
- Traditionally formularies consisted of only three tiers or less. However, an increasing number of plans have created a fourth tier of drug cost sharing, often referred to as a specialty tier, primarily used for expensive drugs
  - Originally developed as part of Medicare Part D, and is now utilized by the majority of commercial plans
- While cost-sharing structures vary among health plans, most require enrollees to pay a set co-payment for drugs in tiers 1-3 and a percentage of the drug's cost (referred to as coinsurance) for those in the fourth tier
- Each individual insurer or payer determines whether a drug is placed on a specialty tier

1. Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2012.

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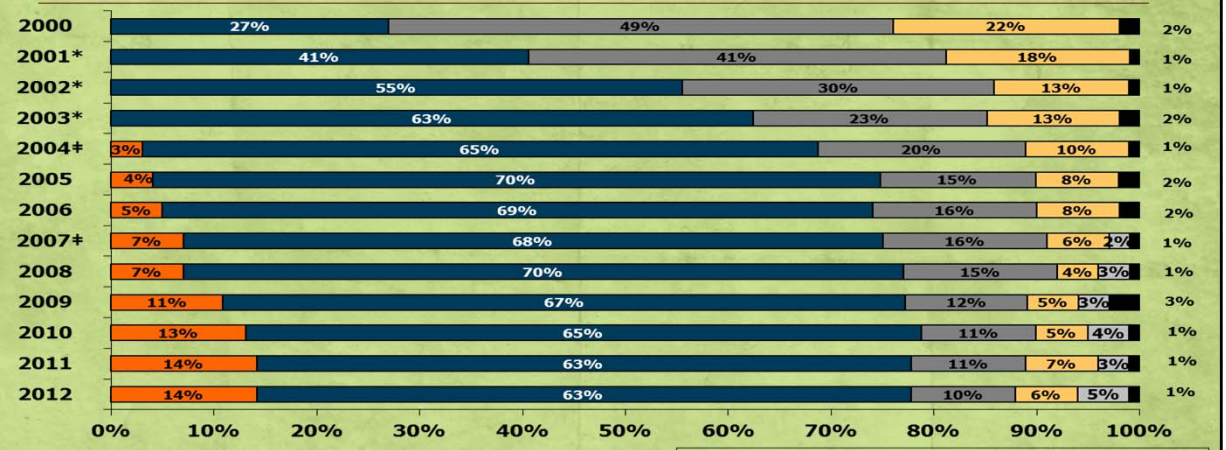
Distribution of Covered Workers Facing Different Cost-Sharing Formulas for Prescription Drug Benefits, 2000-2012



* Distribution is statistically different from distribution for the previous year shown (p<.05).

‡ No statistical tests are conducted between 2003 and 2004 or between 2006 and 2007 due to the addition of a new category.

Note: Fourth-tier drug cost-sharing information was not obtained prior to 2004.

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2000-2012.

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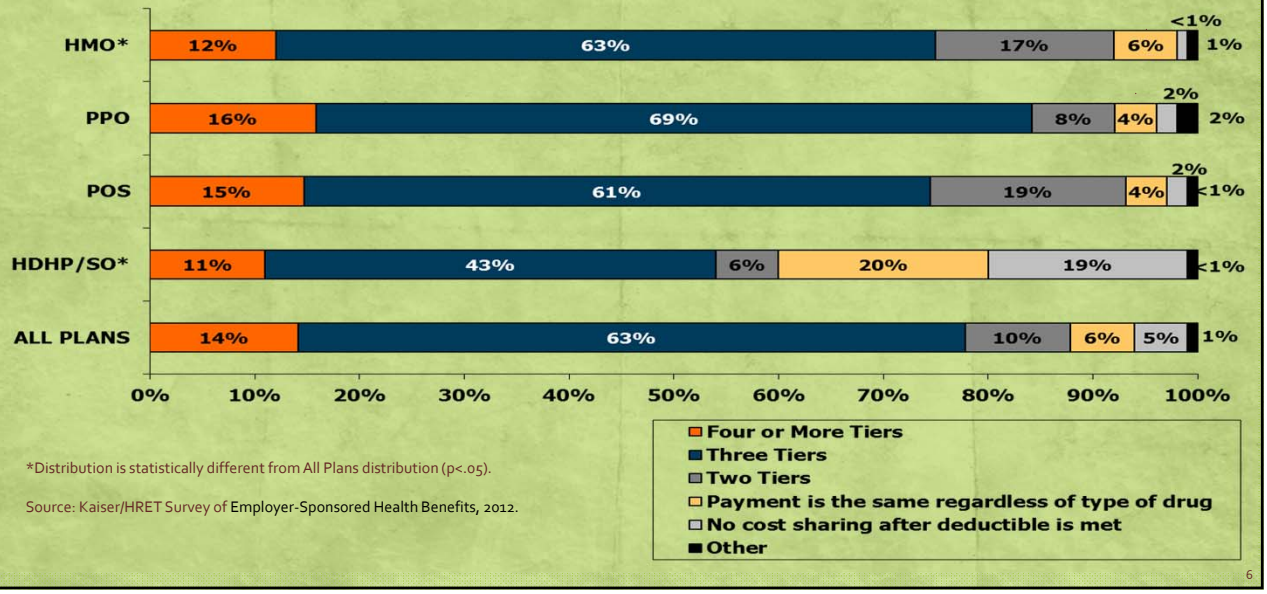
Distribution of Covered Workers Facing Different Cost-Sharing Formulas for Prescription Drug Benefits, by Plan Type, 2012



*Distribution is statistically different from All Plans distribution (p<.05).

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2012.

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Percent of Workers* with the Following Types of Cost Sharing for Prescription Drugs for Each Tier, 2012

	Co-pay	Coinsurance	Some Other Amount
1st Tier	86%	11%	4%
2nd Tier	77%	21%	2%
3rd Tier	72%	24%	4%
4th Tier	55%	36%	10%

*Among covered workers with three or more tiers of cost sharing for prescription drugs.

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2012.

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Among Covered Workers with Three, Four, or More Tiers of Prescription Cost Sharing, Average Copayments and Average Coinsurance by Drug Type, 2000-2012

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Average Copayments													
First-Tier Drugs	$8	$8	$9	$9	$10	$10	$11	$11	$10	$10	$11	$10	$10
Second-Tier Drugs	$15	$16	$18	$20	$22	$23*	$25	$25	$26	$27	$28	$29	$29
Third-Tier Drugs	$29	$28	$32	$35	$38	$40	$43	$43	$46	$46	$49	$49	$51
Fourth-Tier Drugs	^	^	^	^	$59	$74	$59	$71	$75	$85	$89	$91	$79
Average Coinsurance													
First-Tier Drugs	18%	18%	18%	18%	18%	19%	19%	21%	21%	20%	17%	18%	20%
Second-Tier Drugs	NSD	23%	24%	23%	25%	27%	26%	26%	25%	26%	25%	25%	26%
Third-Tier Drugs	28%	33%	40%	34%*	34%	38%	38%	40%	38%	37%	38%	39%	39%
Fourth-Tier Drugs	^	^	^	^	30%	43%	42%	36%	28%	31%	36%	29%	32%

^ Fourth-tier drug copayment or coinsurance information was not obtained prior to 2004.

NSD: Not Sufficient Data.

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2012.

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VAHP Survey of Virginia Health Insurance Carriers, 2012

- Survey was conducted by the Virginia Association of Health Plans (VAHP) to determine the prevalence of specialty tiers in Virginia
- 12 Licensed Health Insurers
  - 1 is not currently operational
  - 3 are Medicaid only
  - 2 did not respond to the survey
  - 5 indicated that they do not offer specialty drug benefits (i.e. Tiers 4 or 5)
  - 1 indicated that tier 4 drug riders are offered
    - This is a small carrier with less than 300,000 Virginia members
    - Percent of plans with tier 4 drug benefits
      - Small group plans: 24%
      - Large group plans: 16%
      - Self-Insured plans: 7%
    - 0.5% of the members with a four tier drug plan have claims for tier 4 drugs

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What are Specialty Tier Medications?

- No standard definition exists for specialty drugs
- Most specialty drugs are biologic—derived from living organisms—in contrast to the majority of conventional medications made from chemical compounds
- Administered by injection, infusion, inhalation, or orally
- Prescribed for 1% of commercial health plan enrollees, but account for 12-16% of commercial pharmacy benefit drug spending[1]
- Most common characteristics of specialty drugs include:
  - High cost:
    - Medicare: Drugs that exceed $600 per month are placed in the specialty tier
    - On average, the monthly cost for a specialty drug is $1200
  - Typically require special handling by the patient or administration by a clinician
  - Used to treat complex conditions
  - Dosage, adherence and side effects usually require careful monitoring to ensure effectiveness and safety

[1] Estimate only includes spending under the pharmacy benefit, not the medical benefit which represents an estimated 55% of total specialty drug spending.
Primary source: Tu, Ha T. and D. Samuel. "Limited Options to Manage Specialty Drug Spending." Health System Change Research Brief. No. 22. April, 2012.

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Top Health Conditions Requiring Specialty Drugs for Treatment and Rates of Prevalence/Incidence, 2011

Conditions	Approximate Population Affected in the U.S.
Inflammatory Conditions	Rheumatoid Arthritis: 1.3 million Crohn's Disease: 500,000
Multiple Sclerosis	400,000
Cancer	1.4 million new cases per year
HIV	1.1 million
Growth Deficiency	Exact prevalence in children unknown. 35,000 adults, 6,000 newly diagnosed/yr
Blood Disorders	Hemophilia A: 1 in 5,000 male births Hemophilia B: 1 in 25,000 male births
Hepatitis C	3.2 million
Transplants	> 163,000 persons living
Respiratory Conditions	Syncytial Virus: 75,000-125,000 infants hospitalized per year
Pulmonary Hypertension	Prevalence unknown. 200,000 hospitalization per year

Sources: Hemophilia Society; Hormone Health Network; Maryland Annual Mandated Health Insurance Services Evaluation. 2011.; MS Society; www.thoracic.org

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Average Cost of Specialty Medications*

Conditions	Prevalence of Use Among Plan Members	Average Cost Per Prescription	# Prescriptions Per User Per Year	Annual Cost	Annual Cost for Patient w/ 32% Coinsurance
Inflammatory Conditions	0.23%	$2,067	7.5	$15,503	$4,961
Multiple Sclerosis	0.10%	$3,116	9.1	$28,356	$9,074
Cancer	0.15%	$3,259	4.5	$14,666	$4,693
HIV	0.10%	$894	16.7	$14,930	$4,778
Growth Deficiency	0.03%	$3,104	7.2	$22,349	$7,152
Blood Disorders	0.31%	$1,013	1.8	$1,823	$583
Hepatitis C	0.02%	$3,371	8.5	$28,654	$9,169
Transplants	0.11%	$335	12.8	$4,288	$1,372
Respiratory Conditions	0.02%	$2,800	6.9	$19,320	$6,182
Pulmonary Hypertension	0.01%	$3,507	9.7	$34,018	$10,886

*NOTE: Many specialty drugs cost significantly more than the average. For example, hemophilia drugs can cost $60,000-$150,000 per year, and Multiple Sclerosis drugs can cost $48,000 per year.

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Example of Specialty Drugs

Medication	Disease	Monthly Cost	25% Coinsurance	32% Coinsurance
Gleevac	Cancer	$4,744	$1,186	$1,518
Fuzeon	HIV	$3,098	$775	$991
Avonex	Multiple Sclerosis	$3,127	$782	$1001
Humira	Rheumatoid Arthritis / Crohn's Disease	$1,906	$476	$610
Enbrel	Psoriasis / Rheumatoid Arthritis	$2,043	$511	$654

Sources: 1. Kris McFalls, http://206.71.177.80/News/Article_2011-10-07.aspx . 2."Rising Cost of Prescription Drugs to Treat Multiple Sclerosis in Upstate New York." Excellus of the BlueCross BlueShield Association. Winter, 2011.

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State Comparison of Patient Cost Sharing for Top 50 High-Cost (>$500) Medications in Commercial Plans, 2008

STATE*	TOTAL FILLS	% THAT ARE SPECIALTY TIER DRUGS	AVERAGE OOP COSTS FOR DRUGS W/ COPAY	AVERAGE OOP COSTS FOR DRUGS W/ COINSURANCE	DIFFERENCE IN OOP COSTS B/W COPAY AND COINSURANCE
Virginia	**34,298**	**18.4%**	**$45.10**	**$299.28**	**564%**
District of Columbia	3,311	9.3%	$36.21	$380.60	951%
Kentucky	16,902	9.26%	$38.55	$174.06	351%
Maryland	25,625	11.48%	$35.92	$391.10	989%
North Carolina	34,102	13.2%	$46.79	$175.94	276%
West Virginia	5,079	16.0%	$39.64	$351.66	787%
U.S.	**1,472,368**	**10.5%**	**$41.66**	**$189.35**	**355%**

* Total number of fills for top 50 high-cost drugs in the state ** Specialty tier is defined as a drug with a coinsurance greater than $0 Source: Thomson Reuters data, 2008

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Many Insured Patients Require Assistance Paying for Their Prescription Drugs

Top Insurance Issues Reported by Patient Advocate Foundation (PAF) Patients from Virginia, 2011	
Co-Pay Assistance: Facility / Doctor Visits	30.0%
Co-Pay Assistance: Pharmaceutical	28.9%
General Benefit / Coverage Questions	11.3%
Inadequate Coverage Options / Underinsured	7.0%
Premium Assistance	7.0%
Benefit Exclusion	4.5%
Co-Pay Assistance: Inability to Afford Medicare Part D Cost Share	3.6%
Medicare Part D Selection / Enrollment Issue	3.0%
Deductible Assistance	2.3%
Inability to Afford Medicaid Cost Share / Spend Down	2.3%

Source: Patient Advocate Foundation

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Number and Percent of Patient Advocate Foundation (PAF) Co-Pay Relief Program Clients by Health Condition, 2011

Health Condition	2010		2011	
	# of VA Patients	% of the Patient Population	# of VA Patients	% of Patient Population
Autoimmune Disorder	36	4.1%	56	2.8%
Cancer	172	19.6%	254	32.6%
Diabetes	10	1.1%	3	4.1%
Hepatitis C	1	0.1%	10	1.8%
Hormone Suppression Therapy	N/A	N/A	1	3.1%
Osteoporosis	74	8.5%	62	3.8%
Pain	37	4.2%	29	3.5%
Rheumatoid Arthritis	46	5.3%	97	3.1%

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Survey of Individuals Living with Multiple Sclerosis in Virginia

- The Virginia chapter of the Multiple Sclerosis Society conducted a survey of individuals living with MS, and 27 responses were received.
- Does your health or pharmacy plan require you to pay a percentage of the cost of your medication?
  - Yes: 59%
  - No: 40%
- If yes, respondents were asked to provide the name of their insurance plan. Eight unique plan names were listed:
  - Blue Cross & Blue Shield/COVA Care
  - United Health Care
  - Anthem
  - Anthem Blue Cross & Blue Shield
  - Aetna
  - Cigna
  - Humana PPO
  - TriCare Prime Retired

Note: It is unclear whether Anthem and Blue Cross/Blue Shield plans actually represent separate plans.

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Survey of Individuals Living with Multiple Sclerosis in Virginia

- What is the monthly cost of your MS disease-modifying therapy:
  - Average cost: $571
  - Range: $0 - $4,100
  - 2 respondents indicated that they have an up-front deductible of $5,000 and $3,075, respectively
- 14 respondents have experienced an increase in their prescription co-pay or out-of-pocket expenses
  - More than a year ago: 3 respondents
  - Within the last year: 8 respondents
  - During the last 6 months: 3 respondents

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Impact of Prescription Drug Cost-Sharing on Individual Health Outcomes

- Coinsurance and specialty tier pricing place significant financial burdens on insured individuals who have chronic health care issues that require expensive prescription drugs for which there is no suitable generic or non-preferred brand equivalent
  - Multiple studies have found that in many cases this leads to decreased adherence or failure to take medications as prescribed, resulting in acute incidents and negative health outcomes. Key findings include:
    - Higher cost-sharing leads to greater use of hospital inpatient and emergency department services for people with chronic illnesses
    - Although 90% of people with MS have some form of health insurance, 20% delayed filling prescriptions, skipped doses, or split pills due to cost
    - Out-of-pocket expenses greater than $100 for tumor necrosis fact (TNF) blocker medications for rheumatoid arthritis, and greater than $200 for MS therapies, were associated with increased prescription abandonment[3]
    - High cost sharing delays the initiation of drug therapy for patients newly diagnosed with chronic disease[1]
      - For rheumatoid arthritis, most of the joint damage occurs in the first three years of the disease, so a delay in therapy increases the risk for lifelong disability. (Doubling the co-pay resulted in 21% reduction in use among people with RA)

Sources: 1. Cost Sharing and the Initiation of Drug Therapy for the Chronically Ill. Arch Intern Med. 2009. 169(8). 2. Meta-Analysis of Trials of Interventions to Improve Medication Adherence. American Journal of Health System Pharmacy. 2003. 60(7). 3. Association of Prescription Abandonment with Cost Share for High-Cost Specialty Pharmacy Medications. J Manag Care Pharm. 2008. 15(8). 4. Patient and Plan Characteristics Affecting Abandonment Rate of Oral Oncoloytic Prescriptions. Journal of Oncology Practice. 7(3). 2011.

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Potential Effect of Health Care Reform on Cost Sharing for Prescription Medications

- Prohibits annual and lifetime limits on the dollar value of essential health benefits
- Limits deductibles in the small group market to $2,000 for single coverage and $4,000 for family coverage (unless other employer contributions offset additional deductible amounts)
- Limits out-of-pocket spending to the cost-sharing levels of the Health Savings Accounts current law limit which CMS estimates will be $6,645 for individuals and $13,290 for families in 2014[1]
  - Includes deductibles, coinsurance, and co-pays associated with the purchase of prescription drugs
- All plans[2] must provide a Summary of Benefits and Coverage (SBC) to "shoppers" upon request and to enrollees, and must include an Internet address where an individual can find more information about the prescription drug coverage under the plan. (Effective 9/23/12)
- Plans and issuers, including self-insured plans[2], are required to provide at least 60 days advance notice of a reduction in covered services or benefits during a contract period
- Effective upon enactment, the ACA authorized the Food and Drug Administration to approve generic versions (i.e. biosimilars) of biologic drugs and granted biologics manufacturers 12 years of exclusive use before generics can be developed.

1. CMS estimates which can be found in the April 22, 2010 Actuarial Study of PPACA 2. A Final Ruling, issued 2/9/12, states that the SBC provisions apply to self-insured plans

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Potential Effect of Health Care Reform on Cost Sharing for Prescription Medications

- There is still a great deal of uncertainty surrounding the details of essential health benefits and the use of a benchmark plan
  - Issued guidelines from HHS have indicated that plans will be allowed to vary from the benchmark plan's benefit design by adjusting benefits and quantity limits and making actuarially equivalent substitutions of benefits within categories, as well as between categories
  - HHS proposes to allow insurers the flexibility to vary formularies as long as the plans cover at least one drug per category and class from the benchmark plan

Sources: 1. CMS Bulletin, "Frequently Asked Questions on Essential Health Benefits Bulletin" issued 2/20/12
2. http://neach.communitycatalyst.org/states/ma/news/your-questions-on-the-essential-health-benefits-bulletin-answered
3. http://www.governing.com/news/federal/gov-hhs-releases-more-details-on-essential-health-benefits-packages.html

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Federal Legislative Action

- Patients' Access to Treatments Act of 2012 (PATA). Rep. David McKinley , WV
  - Limits co-pay, coinsurance or other cost-sharing requirements applicable to prescription drugs in a specialty drug tier to the dollar amount (or its equivalent) of such requirements applicable to drugs in a non-preferred brand drug tier
  - 3/19/2012: Referred to the House Committee on Energy and Commerce
- Part D Beneficiary Appeals Fairness Act. Rep. Henry "Hank" Johnson, GA
  - To amend title XVIII of the Social Security Act to allow for fair application of the exceptions process for drugs in tiers in formularies in prescription drug plans under Medicare part D. Provides seniors on Medicare Part D who rely on 'specialty tier' drugs an appeals process when dealing with the high costs of these prescriptions
  - 12/8/2011: Referred to House Committee on Energy and Commerce
- Transforming the Regulatory Environment to Accelerate Access to Treatment (TREAT) Act. Sen. Kay Hagan, NC
  - Accelerates the review and approval process for medicines that treat an unmet medical need, significantly advance the standard of care, or are highly targeted therapies for serious or life-threatening diseases or conditions
  - Enacted 6/1/12 as part of the Food and Drug Administration Safety and Innovation Act
- President Obama's 2013 budget includes a reduction in years of exclusivity granted to manufactures of biologic drugs from 12 to 7 years and prohibits "Pay for Delay" agreements to increase the availability of generic drugs and biologics

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State Legislative Action

INTENT OF LEGISLATION	STATES	STATUS
Prohibit specialty tiers and/or coinsurance	Alaska*, Delaware*, New York, Vermont*	Passed
	Massachusetts, New York, Pennsylvania, Washington	Active
	California, Kansas, Nebraska	Died
Limit coinsurance, co-pays, deductibles and/or total OOP costs	Maine	Passed
	Connecticut, Hawaii, Indiana, Massachusetts, Rhode Island, Washington	Active
	Arizona, California, Maryland, Nebraska	Died
Require 60 day notice of mid-year benefit reductions	Louisiana, Texas	Passed
	Oklahoma	Active
	Arizona, New Mexico	Died
Study specialty tiers	Delaware, Virginia, West Virginia	Passed
	Illinois	Active

* AK: Limited to high-risk pool, DE and VT: Moratoriums that end in 2012

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Key Considerations

- The original intent of drug tiers, to provide incentives for consumers to consider costs when making health care decisions, is not applicable for specialty drugs for which there are no suitable, less expensive alternatives
  - Instead, drug tiering has created a structure where those who are most sick are required to pay more
  - Specialty tier pricing may not be cost effective for employers in the long run due to increased medical costs that can result from decreases in treatment adherence
- The number of conditions that can be treated with specialty drugs—and thus the number of patients eligible for treatment with these high-cost drugs—are both expected to increase significantly over the next ten years and beyond.
- Biosimilars are expected to reduce drug costs, but their impact will not be seen for many years:
  - Innovator products are granted 12 years of market exclusivity and often are protected by patents lasting longer
  - The FDA approval process, not yet finalized, is expected to be rigorous and lengthy
  - Biosimilars will not reduce drug costs as much as conventional generic drugs. Due to the complexity of the manufacturing process, biosimilars likely will still be far more expensive than most conventional drugs

Primary Sources: 1. Tu, Ha T. and D. Samuel. "Limited Options to Manage Specialty Drug Spending." Health System Change Research Brief. No. 22. April, 2012
2. Express Scripts Drug Trend Report, 2011

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Key Considerations

- Would legislation that places limits on cost sharing for prescription drugs create a new mandate that is subject to the requirement in the ACA that, for coverage provided through the Exchange, the State pay the full cost of any mandate that exceeds the covered services in the Essential Benefits Package (EBP)?
  - Coverage for prescription drugs already is included as one of the ten required essential health benefits
  - Studies conducted in California and Maryland suggest that a bill that restricts forms of cost sharing does not create a mandated covered service; rather it puts restrictions on cost sharing designs that can be used to craft the levels of cost sharing within the EBP for the "metal tiers"
    - California's bill (AB 310) included language that would make the bill inoperative if it were determined that the requirements would result in the assumption by the state of additional costs pursuant to Section 1311(d)(3)(B) of the ACA

Sources: 1. "Analysis of Assembly Bill 310: Prescription Drugs." Report to the 2011-2012 California Legislature by the California Health Benefits Review Program. April 14, 2011. 2. 2011 Session Position Paper by the Maryland Health Care Commission regarding HB 251.

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Policy Options

Option 1: Take no action

Option 2: Include study in the JCHC 2013 work plan in order to review the effects of PPACA, if retained, on cost sharing and specialty tier pricing of prescription medications.

Option 3: Request by letter of the JCHC chairman that the VAHP encourage health insurance carriers to offer monthly payment plans for enrollees who are required to purchase multiple months of a high-cost prescription at one time.

Option 4: Introduce legislation or budget language to prohibit coinsurance (i.e., percentage cost of the prescription) as the basis for cost sharing for outpatient prescription drug benefits, and limit a health insurance enrollee's co-payment for each outpatient prescription drug to $150 per one-month supply or its equivalent for prescriptions for longer periods, adjusted for inflation over time.

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Policy Options

Option 5: Introduce legislation requiring qualified health plans to allow individuals who are expected to incur costs in excess of the cost sharing limits set by the ACA the option of paying their capped out-of-pocket amount in 12 equal installments over the course of the year.

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Public Comments

- Written public comments on the proposed options may be submitted to JCHC by close of business on October 6, 2012. Comments may be submitted via:
  - E-mail: sreid@jchc.virginia.gov
  - Facsimile: 804-786-5538 or
  - Mail to: Joint Commission on Health Care
    P.O. Box 1322
    Richmond, Virginia 23218
- Comments will be summarized and presented during the JCHC meeting on October 16th

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