State Efforts to Lower Consumer Cost-Sharing for High-Cost Prescription Drugs

Stakeholder Perspectives

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August 2017

Federal action to lower the cost of prescription drugs has broad support across the political spectrum. In one recent poll, over 60 percent of Americans identified lowering the cost of prescription drugs as a "top priority" for the Trump administration and Congress (Kirzinger et al. 2017). But to date, there has been little change in federal policy on drug pricing and costs. Perhaps in response to federal inaction on this issue, state legislators have introduced 80 bills in 2017 alone that attempt to lower prescription drug costs. One area of focus for states has been high out-of-pocket drug costs for consumers with chronic conditions such as multiple sclerosis or cancer that require treatment with specialty drugs. California, Colorado, Delaware, Louisiana, Maryland, Montana, New York, and Vermont have leveraged their authority to regulate health insurance to lower cost-sharing charges for consumers using these specialty drugs.

To assess the goals and impact of these state policies, we conducted interviews with regulators, insurers, and consumer advocacy groups in four of the eight states: California, Colorado, Louisiana, and Montana. Most of the stakeholders said that these state policies have had their intended impact by reducing consumers' out-of-pocket costs for expensive prescription drugs and by preventing insurers from discriminating against high-cost enrollees through the design of plan formularies. However, stakeholders had mixed opinions about the policies. Insurer respondents noted that they shift costs to other consumers, either through higher premiums or cost-sharing for other services, and mask the larger problem of escalating drug prices. On the other hand, many consumer advocates support these policies because they help shield consumers with chronic conditions from financial stress and give them easier access to drugs vital to their health and even survival (Pfizer 2015).[1]

Background

Most health plans cover prescription drugs. To constrain costs, insurers often assign different levels of consumer cost-sharing to different categories of prescription drugs in a practice called "tiering." Health plan formularies (lists of covered prescription drugs) commonly have a four-tier structure:

- Tier 1: generic drugs
- Tier 2: preferred-brand drugs
- Tier 3: nonpreferred-brand drugs
- Tier 4: specialty drugs

Enrollees' cost-sharing obligations increase with each tier to give them a financial incentive to use lower-cost drugs.[2] Specialty drugs do not have a uniform definition, but they typically refer to drugs that are expensive, require patient training to use, require special handling and administration such as injections or infusions, and are used to treat complex conditions.[3] Specialty-drug costs for certain conditions, such as cancer and inflammatory conditions like rheumatoid arthritis, can average more than $50,000 a year; prices of $100,000 or more a year are not uncommon (Pew Charitable Trusts 2015; Schondelmeyer and Purvis 2015).[4] Specialty drugs for some chronic conditions have no lower-cost alternatives; for example, the only medications available to treat multiple sclerosis have an average price of $60,000 a year.[5] More than half of commercial health plans place specialty drugs in a separate tier and require the enrollee to pay coinsurance (a percentage of the total cost) rather than a set dollar amount or copayment (PBMI 2016).[6] Coinsurance amounts can range from 20 to 40 percent.[7] Coinsurance for specialty drugs can make treatment budgeting a challenge for consumers because the out-of-pocket amount is a percentage of the drug cost, which varies by drug.

The Affordable Care Act (ACA) provides significant financial protections for consumers with out-of-pocket prescription drug costs. First, the law requires all health plans in the individual and small-group markets to cover prescription drugs according to a minimum or "essential" health benefit standard.[8] Second, the law prohibits health plans from placing financial lifetime or annual limits on any essential health benefits for group or nongroup coverage.[9] Third, the ACA places a cap on enrollees' annual out-of-pocket costs for group and nongroup coverage; in 2017, the maximum amount an individual enrollee can pay out-of-pocket for covered benefits is $7,150.[10] Though these protections help stave off catastrophic expenses, many consumers still face high and rising costs as drug prices rise and insurers shift more of those costs onto enrollees. Thus, up-front out-of-pocket costs for one or two specialty drugs may become unaffordable for many consumers, causing them to forgo needed treatment, skip prescriptions, or face significant financial hardship (Briesacher, Gurwitz, and Soumerai 2007; Collins et al. 2013; Hamel et al. 2016; Himmelstein et al. 2009).[11]

BOX 1

ACA Financial Protections That Limit Prescription Drug Costs

- Mandatory coverage of prescription drugs as an essential health benefit in individual and small-group health plans
- No lifetime or annual limits on coverage of prescription drugs or other essential health benefits in group or nongroup insurance
- Limit on consumers' annual out-of-pocket costs under group and nongroup insurance

These trends have put political pressure on state governments to enact policies to protect consumers from high drug prices and associated cost-sharing. But the federal government has jurisdiction over how prescription drugs enter the market and move through interstate commerce, limiting the extent to which states can regulate in this area.[12] To date, there has been little federal action on drug costs (with the exception of the Medicaid prescription drug rebate program, which has helped offset drug costs for federal and state governments).[13] In the absence of a federal policy to lower drug costs, several states have leveraged their authority over health insurance products to protect consumers from high out-of-pocket costs for expensive prescription drugs. California, Colorado, Delaware, Louisiana, Maryland, Montana, New York, and Vermont have placed limits on consumers' out-of-pocket costs for prescription or specialty drugs (table 1).[14] We identified these policies through a survey of laws in 50 states and the District of Columbia.

TABLE 1

State Actions to Protect Plan Enrollees from High Out-of-Pocket Costs for Prescription or Specialty Drugs as of January 2017

State	Applicable markets	Effective date	Type	Cap	Deductible limit
California[a]	Individual Small-group Large-group	2017	Statutory	$250/month $500 in bronze plans	$500 $1,000 in bronze plans
Colorado[b]	Individual Small-group	2016	Administrative	No	No
Delaware[c]	Individual Small-group Large-group	2014	Statutory	$150/month for specialty drugs	No
Louisiana[d]	Individual Small-group Large-group	2015	Statutory	$150/month for specialty drugs	No
Maryland[e]	Individual Small-group Large-group	2014	Statutory	$150/month for specialty drugs	No
Montana[f]	Individual, Marketplace only	2015	Administrative	No	No

State	Applicable markets	Effective date	Type	Cap	Deductible limit
	Small-group, Marketplace only				
New York[g]	Individual Small-group Large-group	2010	Statutory	No	No
Vermont[h]	Individual Small-group Large-group	2012	Statutory	$1,300/year for individual $2,600/year for family	No

Sources: Cal. Insur. Code §§ 10123.193 and 1342.71; Co. Insur. Bulletin No. B-4.82; Del. Code Ann. tit. 18 §§ 3364 and 3580; La. Rev. Stat. Ann. § 22:1060.5; Md. Code Ann., Ins. §§ 15-842 and 15-847; Mont. Memorandum 3-8-2015; NY Insur. Law §§ 3216 and 3221, NY Public Health Law § 4406-c; and Vt. Stat. Ann., tit. 8 § 4089i. See also: Sabrina Corlette, Ashley Williams, and Justin Giovannelli, "State Efforts to Reduce Consumers' Cost-Sharing for Prescription Drugs," *To the Point* (blog), Commonwealth Fund, November 16, 2015, http://www.commonwealthfund.org/publications/blog/2015/nov/state-efforts-to-reduce-consumers-cost-sharing-for-prescription-drugs.

[a] California's cap applies after the deductible has been met for a high-deductible health plan (defined in federal law as having an annual deductible of $1,300 for individual coverage or $2,600 for family coverage in 2017).

[b] Colorado's guidance also prohibits insurers from placing all specialty drugs for a disease on a specialty tier; requires insurers to offer at least one plan design with a predeductible copayment structure in each metal tier; and allows remaining plans to have a coinsurance structure as long as they constitute no more than 75 percent of plans; and limits copays to 1/12 of a plan's out-of-pocket limit. The guidance does not apply to high-deductible health plans (defined in federal law as having an annual deductible of $1,300 for individual coverage or $2,600 for family coverage in 2017).

[c] Delaware prohibits the placement of all specialty drugs for a disease on a specialty tier.

[d] Louisiana's cap applies after the deductible and maximum out-of-pocket cost have been met.

[e] Under Maryland law, the cost-sharing limit for specialty drugs increases annually, indexed to inflation. Maryland also prohibits copayments or coinsurance from exceeding the retail price of the prescription drug.

[f] Montana requires health plans to provide one plan design with an all-copayment structure without a prescription deductible.

[g] New York's law prohibits specialty drug tiers.

[h] Vermont sets the annual cap to the deductible for high-deductible health plans (defined in federal law as having an annual deductible of $1,300 for individual coverage or $2,600 for family coverage in 2017).

Of the eight states, all but two passed legislation to implement their policies; Colorado and Montana's departments of insurance issued their policies through administrative guidance.[15] Five of the eight states enacted monthly or yearly limits on consumers' cost-sharing. For example, Delaware limits cost-sharing to $150 for a 30-day supply of specialty drugs and prohibits insurers from placing all their specialty drugs for a disease on a specialty tier. Vermont imposes an annual out-of-pocket cap of $1,300 for individual enrollees. Colorado, Montana, and New York use other plan design requirements to limit enrollees' costs: In Montana, insurers offering health plans on the health insurance Marketplace must offer at least one plan with a copayment structure for all drug tiers and no deductible. New York prohibits insurers from having any specialty tier in their drug formularies.[16]

Stakeholder Observations

To assess why states enacted their policies to limit enrollees' out-of-pocket costs for prescription and specialty drugs and the impact of these policies, we conducted structured interviews with state regulators and representatives from insurance companies and consumer advocacy groups in California, Colorado, Louisiana, and Montana.

Most States Enacted Policies to Protect Vulnerable Enrollees from High Cost-Sharing and Benefit Design Discrimination

Legislative history and stakeholder interviews demonstrate that across the eight states, these policies were developed to lower the financial burden for residents with chronic diseases who need high-cost specialty drugs.[17] For example, the laws in Delaware and New York refer to the increasing costs of specialty drugs and the corresponding "significant financial strain" on residents with chronic conditions as the impetus for enacting the policies.[18] State regulators in Colorado and Montana noted that high drug cost-sharing "exposed [consumers] to their full maximum-out-of-pocket costs in any one month" or "all at once at the beginning of the year," and intended their policies to help spread "that cost over the entire year" so that residents with chronic conditions could afford their medications.

The administrative and legislative records in California, Colorado, Montana, and New York show the discriminatory effect of placing specialty drugs on the highest-cost drug tier for people with chronic diseases.[19] California and Colorado's policies rely on the ACA's prohibition of discriminatory plan benefit designs that would "discourage enrollment" of people with health conditions.[20] New York's policy, passed before the ACA was enacted, describes the "extraordinary disparity" of cost-sharing for consumers who need specialty drugs as part of its rationale for banning specialty drug tiers altogether.[21] According to regulator and insurer respondents in Montana, regulators used their authority to regulate contracts and fair trade to issue the state's administrative guidance, pegging new formulary requirements to state-level prohibitions on discrimination.

Patient Advocacy Groups and Drug Manufacturers Shaped State Policies

The political impetus for action in the eight study states largely came from groups representing patients with diseases such as multiple sclerosis and cancer, but it was buttressed by the advocacy efforts of prescription drug manufacturers. California patient advocates were important in initiating and developing state policy through Covered California (the state Marketplace) and worked with the legislature to expand the policy's scope from Marketplace plans to the entire market. However, one California insurer noted that some patient advocacy groups are funded partially or fully by pharmaceutical companies. "They [pharmaceutical manufacturers] have enormous influence," the insurer said.

In Louisiana, a major pharmaceutical company led the initiative to enact the state's cost-sharing policy. An insurer respondent said that his company initially opposed it because it did not lower the

prices of prescription drugs. However, as the proposal gained traction with the legislature, the insurer decided to work with the bill's sponsor. Insurer representatives negotiated changes to the bill, removing the prohibition on specialty drug tiers with coinsurance and eliminating the $1,000 annual cap on a consumer's out-of-pocket prescription drug costs.[22] The insurer respondent deemed the $150 monthly cap "too low," but felt that the company "ended up in an okay spot."

Insurers in California, Colorado, and Louisiana reported being part of policy development on this issue, but an insurer respondent in Montana had a different experience. The insurer said that in the past they had had "a [policy development] process with public hearings and we were able to make comments," but "this was not done that way."

State Policies' Effect on Premiums and Utilization Is Unclear

Respondents said they did not have data yet on whether these state policies drive up use of specialty drugs. An insurer respondent in Montana observed that "specialty costs have increased significantly, but you can't blame it on this policy," pointing to a nationwide increase in specialty drug use.

Capping out-of-pocket costs for specialty-tier drugs may result in increased premiums (Milliman 2015; NAIC 2016).[23] A review of actuarial memoranda justifying insurer premium rate increases in four study states indicates minor premium increases as a result of caps in two states.[24] One insurer in California noted that the Marketplace's cost-sharing limits for specialty drugs "increased expected pharmacy costs in 2016 relative to 2015."[25] Similarly, an insurer in Colorado said that the state requirement to offer at least one copayment structure for prescriptions had a "small pricing impact."[26] However, these actuarial memoranda did not specify the amount of premium increase directly attributable to these policies.

Insurers had different takes on the impact on premiums. A Montana insurer said that state policy increased its premiums by 2 percent: "It doesn't sound like a lot, but that's quite a bit. Pharmacy is a huge cost driver and it increased our pharmacy costs, but we only added 2 percent to the plan premium."[27] One California insurer said it was "too soon to tell" the impact of the state's cost-sharing limit, but estimated that the policy "will indeed have the effect" of a 1 to 3 percent increase in premiums, similar to the increase projected by actuarial studies. California officials estimated that the state's cost-sharing limit would raise premiums 1 percent from 2015 to 2016 (Covered California 2015a; Milliman 2015), but it is unclear if they actually did so. Colorado regulators felt the policy had a "little bit of an impact because of the cost-sharing structure" but have not completed an analysis. A Colorado insurer said that the policy did not increase premiums and that "from a net actuarial standpoint, this was a modest reduction in plan benefits," because the plan had already capped member cost-sharing for specialty drugs.[28]

Stakeholders in Colorado and Louisiana suggested that their state policies had not achieved their intended impact. A Colorado consumer advocate wondered if the policy "moved the needle far enough" because coinsurance structures may still discriminate against people with high medication needs, discouraging them from enrolling in certain plans. Louisiana regulators were uncertain about the state

policy's effectiveness in reducing costs for consumers. Because Louisiana's policy only applies if the plan formulary includes a specialty tier, insurers are placing their specialty drugs in other tiers, which may require coinsurance without a monthly cap on out-of-pocket costs. As one regulator put it, "There's a loophole, and it was quickly found." State regulators tried to enforce the policy on specialty drugs regardless of where insurers placed them on a formulary tier, but insurers pushed back, citing the language of the law. One regulator said the bill "would have been more helpful if it had been written for specialty drugs regardless of tier."

Most insurer respondents agreed that their state policies insulate enrollees with chronic diseases from high out-of-pocket costs, particularly for specialty drugs, and allow enrollees to budget their medication costs throughout the year. Insurers generally agreed "it's not bad public policy," but reiterated that these policies mask consumer awareness of the high cost of specialty drugs. One insurer noted that "there is no general outcry for drug manufacturers to look at their cost structure," a sentiment other insurers echoed. Another insurer stated that "you can make a strong case that we have made things worse" with the state limit on out-of-pocket costs for prescription drugs because the policy "preserves their [drug companies'] ability to charge the moon." Other respondents noted that consumers suffering from chronic diseases should not bear the brunt of high drug costs and that the problem of the high price of prescriptions "cannot be solved by making necessary drugs unaffordable."

Looking Ahead

Recent congressional proposals to replace the ACA would have allowed states to waive the requirement that insurers cover prescription drugs and would have increased the cost-sharing consumers face for drugs and services. Under such policies, consumers with chronic conditions who need high-cost specialty drugs would face substantial new financial barriers to obtaining treatment.

Our 50-state review of laws regulating consumer cost-sharing for prescription drugs and our follow-up interviews with stakeholders in four states suggest that these policies can help shield consumers with chronic conditions from financial barriers that, in many cases, cause them to forgo or delay care, potentially worsening health outcomes. But these policies are not cost-free. By reducing out-of-pocket costs for a subset of highly vulnerable enrollees, they may have also caused some insurers to increase premiums for all their enrollees or cost-sharing for other drugs and services. Insurers pointed out that these policies do nothing to lower the underlying prices drug manufacturers charge for their products, and insulating consumers from the high costs of specialty drugs could dampen the public outcry for action on high prescription drug prices.

Ultimately, these states have developed policies that relieve high-risk patients from extremely high drug costs by spreading those costs across a broader risk pool including healthy and sick people. For many patients in need of specialty drugs, that kind of risk-spreading means they no longer have to forgo those drugs or experience financial hardship to obtain treatment. With emerging federal policies that could lead to higher cost-sharing for many health plan enrollees, more states may adopt insurance standards to protect vulnerable consumers who need high-cost medications.

Notes

1. See also: Alex Wayne, "Drugmakers Turn Heat on Insurers by Backing Copay Limits," *Bloomberg*, March 12, 2015, https://www.bloomberg.com/news/articles/2015-03-12/drugmakers-turn-heat-on-insurers-by-backing-copay-limits-health.
2. Eighty-eight percent of covered workers are in plans that use drug tiering (Claxton et al. 2016). Nearly all silver plans in the federal Marketplace use drug tiering; see Caroline F. Pearson, "2016 Exchange Plans Improve Access to Medicines Used to Treat Complex Diseases," press release, Avalere Health, April 19, 2016.
3. Medicare has a monetary threshold of $600 or more per month as part of its specialty drug definition (Kirchhoff 2015).
4. Carolyn Y. Johnson, "Specialty Drugs Now Cost More than the Median Household Income," *Wonkblog, Washington Post*, November 20, 2015, https://www.washingtonpost.com/news/wonk/wp/2015/11/20/specialty-drugs-now-cost-more-than-most-household-incomes/.
5. Richard Harris, "Multiple Sclerosis Patients Stressed Out by Soaring Drug Costs," *Shots* (blog), NPR, May 25, 2015, http://www.npr.org/sections/health-shots/2015/05/25/408021704/multiple-sclerosis-patients-stressed-out-by-soaring-drug-costs.
6. Pearson, "2016 Exchange Plans."
7. In 2016, nearly half of employer-sponsored health plans required coinsurance for specialty drugs, with an average coinsurance rate of 26 percent. For health plans sold through Marketplaces established under the ACA, coinsurance was the most common type of cost-sharing for specialty drugs, with coinsurance rates ranging from 32 to 37 percent (Claxton et al. 2016; Rae et al. 2015).
8. 42 U.S.C. 300gg-6 (codifying § 2707 of the Patient Protection and Affordable Care Act, Pub. L. 111-148).
9. 42 U.S.C. 300gg-11 (codifying § 2711 of the Patient Protection and Affordable Care Act, Pub. L. 111-148).
10. 42 U.S.C. 18022 (codifying § 1302 of the Patient Protection and Affordable Care Act, Pub. L. 111-148). 81 Fed. Reg. 12204. Patient Protection and Affordable Care Act. HHS Notice of Benefit and Patient Payment Parameters; Final Rule. March 8, 2016.
11. Collins and colleagues (2013) found that the cost of filling a prescription kept more than two in five adults from getting the medication. Similarly, half of survey respondents with medical bills reported having problems paying for their prescription drugs.
12. National Academy for State Health Policy, "Update: What's New in State Drug Pricing Legislation?," *State Health Policy Blog*, National Academy for State Health Policy, May 1, 2017, http://nashp.org/update-whats-new-in-state-drug-pricing-legislation/. Most legislative proposals require drug manufacturers to make prescription drug pricing or price increases more transparent or deter them from price "gouging."
13. 42 U.S.C. 1396r-8.
14. Cal. Insur. Code §§ 10123.193 and 1342.71; Co. Insur. Bulletin No. B-4.82; Del. Code Ann. tit. 18 §§ 3364 and 3580; La. Rev. Stat. Ann. § 22:1060.5; Md. Code Ann., Ins. §§ 15-842 and 15-847; Mont. Memorandum 3-8-2015; NY Insur. Law §§ 3216 and 3221, NY Public Health Law § 4406-c; and Vt. Stat. Ann., tit. 8 § 4089i. See also: Sabrina Corlette, Ashley Williams, and Justin Giovannelli, "State Efforts to Reduce Consumers' Cost-Sharing for Prescription Drugs," *To the Point* (blog), Commonwealth Fund, November 16, 2015, http://www.commonwealthfund.org/publications/blog/2015/nov/state-efforts-to-reduce-consumers-cost-sharing-for-prescription-drugs.
15. See note 14.
16. 42 U.S.C. 1396r-8.
17. Cal. Insur. Code §§ 10123.193 and 1342.71; 2015 Cal. Legis. Serv. Ch. 619 (A.B. 339); Co. Insur. Bulletin No. B-4.82; DE Legis. 133 (2013), 2013 Delaware Laws Ch. 133 (S.B. 35); H.B. 761, Gen. Assembly (2014 Sess.) Fiscal and Policy Note, Maryland Dept. of Legislative Services; LA Leg. (2014 Reg. Sess.), S.B. 165; Mont.

Memorandum 3-8-2015; NY Sen. Assembly (2009-2010 Sess), S.B. 68004; VT Legis. (2011-12) H.B.559; and officials in Colorado and Montana departments of insurance, interviews with authors, November 2016 – January 2017 . See also: Karen Kennedy, letter to the editor, *Times-Picayune*, May 5, 2015, http://www.nola.com/opinions/index.ssf/2014/05/bill_would_save_patients_hundr.html.

18. DE Legis. 133 (2013), 2013 Delaware Laws Ch. 133 (S.B. 35); NY Sen. Assembly (2009–10 Sess.), S.B. 68004.
19. Cal. Insur. Code §§ 10123.193 and 1342.71; 2015 Cal. Legis. Serv. Ch. 619 (A.B. 339); Co. Insur. Bulletin No. B-4.82; NY Sen. Assembly (2009–10 Sess.), S.B. 68004; Mont. Memorandum 3-8-2015; and officials in Colorado and Montana departments of insurance, interviews with authors, November 2016 to January 2017.
20. 45 C.F.R. § 156.125. Cal. Insur. Code §§ 10123.193 and 1342.71; 2015 Cal. Legis. Serv. Ch. 619 (A.B. 339); Co. Insur. Bulletin No. B-4.82.
21. NY Sen. Assembly (2009–10 Sess.), S.B. 68004.
22. La. Senate (40th Reg. Sess.), 2014 S.B. 165 (introduced).
23. Joseph Burns, "Cap On, Premiums Up," *Managed Care*, April 2016, https://www.managedcaremag.com/archives/2016/4/cap-premiums.
24. We reviewed actuarial memoranda at ratereview.healthcare.gov for insurers in California , Colorado, Louisiana, and Montana for the year in which the state's policy went into effect.
25. We reviewed actuarial memoranda at ratereview.healthcare.gov for California insurers with the highest Marketplace enrollment for 2016.
26. We reviewed actuarial memoranda at ratereview.healthcare.gov for nine Marketplace insurers for 2016.
27. For 2015, the average rate increase in Montana was 1.35 percent for a 40-year-old across all the state's geographic zones. For the individual market, the average rate increase was 1.60 percent. See Montana Commissioner of Securities and Insurance, "Montana Sees Historically Low Rate Increases in 2015," press release, August 27, 2014, http://csimt.gov/news/montana-sees-historically-low-rate-increases-2015/.
28. For 2016, the average rate increase for California's Marketplace was 4 percent (Covered California 2015b).

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Acknowledgments

This brief was funded by the Robert Wood Johnson Foundation's Policies for Action program, for which Urban serves as one of five research hubs. We are grateful to them and to all our funders, who make it possible for Urban to advance its mission.

The views expressed are those of the authors and should not be attributed to the Urban Institute, its trustees, or its funders. Funders do not determine research findings or the insights and recommendations of Urban experts. Further information on the Urban Institute's funding principles is available at www.urban.org/support.

The authors would like to thank the respondents who participated in discussions for this issue brief. Findings and conclusions are the authors' alone and should not be attributed to the respondents. The authors are also grateful to Linda Blumberg, John Holahan, Lisa Dubay, and Kevin Lucia for their thoughtful review and comments, and to Emma Chapman, Julia Embry, and Rachel Schwab for their research support.

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