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Improving The Affordability Of Specialty Drugs By Addressing Patients' Out-Of-Pocket Spending

ABSTRACT Spending on outpatient prescription drugs has increased dramatically in recent years. At the same time, the affordability of specialty drugs has eroded, in part because of cost-sharing provisions on commercial insurance and Medicare Part D plans. In this brief we focus on patients facing high out-of-pocket spending for prescription drugs as a result of the growing use of deductibles and coinsurance. We discuss how current cost-sharing provisions and high drug prices threaten the affordability of drugs, and we provide policy recommendations to ensure greater out-of-pocket cost protection for patients. Solutions that limit Medicare beneficiaries' total spending on drugs or enhance pre-deductible coverage for chronically used medications under Medicare and commercial plans may be politically feasible. Policies that include consideration of value for establishing cost sharing and coverage are more challenging to implement but may be a more promising long-term strategy.

Spending on outpatient prescription drugs has increased markedly in recent years. National health spending for retail prescription drugs (excluding physician-administered drugs) totaled $328.6 billion in 2016 following two years of notable spending growth.[1] Much of this spending growth is attributed to the rise in the use of so-called specialty drugs.[2,3] The Centers for Medicare and Medicaid Services (CMS) defines a product as "specialty-tier eligible" when the sponsor-negotiated price is $670 per month or more.[4] However, most specialty drug spending is concentrated on products used for rare, complex, and life-threatening conditions. These products include medications for HIV (average monthly price per fill: $1,556), inflammatory conditions ($3,588), multiple sclerosis ($5,056), oncology ($7,891), and hepatitis C ($15,708).[2] Among drugs offered through outpatient pharmacy benefits, specialty drugs currently make up only 1–2 percent of use but 40–50 percent of drug spending,[2,5] making them an important target for payers and policy makers alike.

Recent drug price increases and insurance coverage changes threaten patients' access to specialty drugs by reducing their affordability. High prices may create incentives for plans to reduce the generosity of coverage for some products, as has been noted for high-price drugs offered under the Medicare Part D benefit[6–10] and through the growing use of deductibles and coinsurance among commercial payers.[11,12]

One of the principal concerns related to the rise in direct patient cost sharing for specialty drugs is severe personal or family financial burden because of illness,

a problem that has been termed "financial toxicity." Commonly reported "symptoms" of financial toxicity include exhausting savings accounts, having to remortgage a home, needing to borrow money from family or friends, or seeking bankruptcy protection.[13] Financial toxicity is associated with nonadherence to medications,[14–22] and there is emerging evidence that it adversely affects quality of life and survival.[23] It is also well documented that higher cost sharing or unexpected changes in costs for prescription drugs can reduce patients' uptake of and adherence to treatments, including specialty drugs.[10,14,15,24–32]

In this brief we document how some of the cost-sharing provisions in commercial insurance and Medicare Part D plans have led to higher out-of-pocket spending and unprecedented levels of financial toxicity for patients needing specialty medications. Because coverage policies regarding pharmacy benefits can differ from those for medical benefits, we focus on prescription drugs offered under out-patient pharmacy benefits and Medicare Part D, excluding physician-administered drugs. We provide several policy solutions to improve the affordability of specialty drugs by targeting patients' out-of-pocket spending. We also suggest methods that payers may consider to align the generosity of coverage with a drug's value in terms of both clinical benefit and cost.

> "Much of this spending growth is attributed to the rise in use of specialty drugs."

Drug Coverage In The US

In 2016 private health insurance and Medicare accounted for 43 percent and 29 percent of retail drug spending, respectively.[1] Cost sharing—the requirement that patients contribute financially to services obtained when using their health insurance—has historically served the purpose of reducing "moral hazard," or the overuse of services that are provided at a low marginal cost.[33] However, the level of cost sharing required for specialty medications has risen in recent years and may undermine the appropriate use of specialty drugs. Ideally, cost sharing should be designed to steer patients toward the most cost-effective treatments when more than one treatment exists. In the case of relatively expensive specialty medications, for which therapeutic alternatives are limited or nonexistent, cost-sharing requirements may serve mainly to impede access to treatment altogether rather than to deter "overuse."

Contributing to the increase in cost sharing, both commercial and Medicare Part D plans have shifted away from copayments (where the patient pays a flat dollar amount per prescription) and toward greater reliance on deductibles (where the patient pays 100 percent of the drug's negotiated price until the deductible is met) and coinsurance (where the patient pays a predetermined percentage of the drug price).

COMMERCIAL INSURANCE

In 2016, 196 million Americans had commercial health insurance,[1] and most plans covered prescription drugs.[34] Coverage of prescription drugs in commercial insurance plans varies widely, but most require some form of patient cost sharing, with different tiers for generics, brands, and specialty drugs. Commercial plans also typically have a maximum out-of-pocket limit for cost sharing, which applies to prescription drug coverage. For example, for commercial plans sold through exchanges created under the Affordable Care Act (ACA), the limit was $7,150 for an individual and $14,300 for a family in 2017.[35]

For people in exchange (Marketplace) plans, exposure to out-of-pocket prescription expenses can vary, despite standardization of policies by metal tiers, annual maximums on out-of-pocket spending, and the availability of cost-sharing subsidies for beneficiaries with incomes between 100 and 250 percent of the federal poverty level.[35] Most bronze plans (lower-premium plans with the lowest actuarial value) have combined medical and prescription drug deductibles that do not begin to cover an enrollee's costs until the deductible has been met. In bronze plans, the average combined deductible was more than $5,700 in 2016.[36] However, most silver, gold, and platinum plans have separate medical and drug deductibles (or no deductible for drugs); for these plans, the average

deductibles ranged from $12 in platinum plans to $404 in bronze plans in 2016.[36]

Patients in employer-sponsored plans are now paying more of their out-of-pocket expenses for retail prescriptions in the form of deductibles and coinsurance, as opposed to copays. For example, deductibles grew from 4 percent of cost-sharing payments in 2004 to 24 percent in 2014; coinsurance increased from 3 percent to 20 percent over that same period.[37] In 2014 an estimated 10-15 percent of people with drug coverage through employer-sponsored coverage who are treated for one of several high-cost conditions (cancer, mental illness, digestive disease, or endocrine, circulatory or blood disorders) spent over $5,000 annually out of pocket on retail and nonretail drugs.[38]

MEDICARE

Since 2006 Medicare has offered voluntary prescription drug coverage to seniors and younger adults with permanent disabilities through the Part D program. In 2017, over 70 percent of Medicare beneficiaries received prescription drug coverage under Part D (through either a private, stand-alone Part D plan or a Medicare Advantage plan that includes the Part D benefit), rather than through an employer-sponsored retiree benefit or other coverage source.[38]

In general, plans must include on their formularies at least two drugs in every drug class, but plans vary in terms of their specific benefit design, cost-sharing amounts, utilization management tools, and covered drugs. In 2017 a majority of Part D enrollees are in plans with a separate tier for specialty drugs, with coinsurance ranging from 25 percent to 33 percent in the initial coverage phase.[39] Beneficiaries with low incomes and modest assets are eligible for assistance with Part D plan premiums and cost sharing, but most Part D enrollees (68 percent in 2015) do not receive this assistance.[38]

In 2017 the standard Part D benefit included four phases: a $400 deductible; an initial coverage phase with coinsurance of 25 percent until drug spending reaches $3,700; a "coverage gap" with coinsurance of 40 percent until total out-of-pocket spending reaches $4,950; and catastrophic coverage, in which the beneficiary is responsible for paying up to 5 percent of their medication costs for the remainder of the year.

Beneficiaries who do not receive low-income subsidies can face substantial out-of-pocket spending for prescriptions, particularly if they use expensive specialty drugs or multiple higher-cost brand-name drugs.[7,40,41] Unlike most commercial drug benefit plans, Part D does not include a hard, annual cap on out-of-pocket expenses. When beneficiaries take medications costing tens of thousands of dollars per year or more, their out-of-pocket spending in the catastrophic phase can exceed their spending in the other benefit phases combined.[40] Because progression through the Part D benefit relies almost exclusively on percentage-based cost sharing for specialty drugs, rising drug prices result in more beneficiaries facing the coverage gap and catastrophic phases of the benefit over time.[41–43]

> "A majority of Part D enrollees are in plans with a separate tier for specialty drugs."

Furthermore, most plans use drugs' point-of-sale prices—instead of net prices that are achieved as a result of plan negotiated rebates—as the basis for calculating patient cost sharing and progression through the Part D benefit.[43] This is a key contributor to the higher proportion of beneficiaries entering the catastrophic coverage phase of the benefit over time, from 17 percent of non–low-income subsidy enrollees in 2007 to 26 percent in 2014.[44,45]

Proposed Policy Solutions

Given current and potentially increasing affordability challenges for Medicare beneficiaries and commercial plan enrollees who need specialty drugs, we suggest several options to reduce financial toxicity among patients and potential challenges to consider.

USE COPAYMENTS INSTEAD OF COINSURANCE

The use of copayments for preferred drugs—instead of coinsurance and deductibles—may improve patients' access and adherence to treatments by providing more predictability for out-of-pocket expenses for those with chronic medication needs.

There are two primary challenges related to the proposal to use copayments instead of coinsurance. First, patients may be less price-sensitive when paying a copayment than when their out-of-pocket payment is proportional to a drug's price. However, plans may still differentiate between preferred and nonpreferred products through use of copayment tiers (with lower copayments for preferred products) to steer patients to more cost-effective treatments when competitors exist within a specialty drug class. Second, implementing this proposal within Medicare Part D would require a statutory change to the standard benefit design, which currently requires coinsurance during the coverage gap, regardless of a plan's cost-sharing design in the initial coverage phase.

SHARE REBATES WITH PATIENTS

Another option for managing patient cost sharing under Medicare or private drug plans is to base it on the plan's net prices (post-rebate) for drugs rather than on drug prices at the point of sale (before rebates and price concessions are received).[46] For branded specialty drugs with competitors, rebates obtained by health plans and pharmacy benefit managers may be substantial, yet patients paying deductibles and coinsurance for these drugs do not benefit from such price reductions directly. There is a stunning lack of transparency about the magnitude of rebates under current arrangements, which places consumers of specialty drugs at a disadvantage. Plans argue that rebates are used to hold down premium costs for all insured people, but this may happen at the direct expense of patients needing high-price specialty drugs.

To reduce out-of-pocket spending for patients paying coinsurance or deductibles, plans could pass through estimated rebates to the patient directly at the point of sale. Importantly, pass-through of rebates would provide savings to Medicare Part D enrollees in each benefit phase without requiring modifications of the standard benefit design. For drugs with multiple treatment options—where rebates are thought to be large—this could result in substantial cost savings for patients using these drugs.

> "Recently, there has been increased focus on value-based formularies for prescription drugs."

There are several challenges to this method of reducing patient cost sharing. First, plans would need to estimate the size of the rebate at the point of sale for an individual product, which would likely increase administrative burden. Second, rebates might not be large for some drugs, including specialty drugs that have limited competitors, meaning that cost savings for patients who take those drugs would be minimal. Third, although empirical evidence is limited, it is possible that disclosing rebates for individual products or payers could disadvantage payers' negotiations, potentially resulting in higher prices (lower rebates). To mitigate this concern, payers could be required to provide access to discounted (post-rebate) prices that have been aggregated in some form across types of drugs to prevent disclosure of product-specific rebates. Finally, to the extent that plans currently use rebates to offset total premium costs, passing through rebates at the point of sale instead may result in an increase in premiums across all members.

ALIGN COST SHARING TO REFLECT VALUE

Recently, there has been increased focus on value-based formularies for prescription drugs (also known as value-based insurance design).[47] For drugs that provide high value for preventing disease or managing disease progression, payers could use benefit design to reduce the chances of nonadherence or treatment interruption. Drugs used to prevent chronic disease progression or complications could be exempt from deductibles or subject to preferred (or zero) cost sharing. Doing so would ensure that patients needing ongoing medication therapy could continue to receive treatment without cost-related disruptions that could occur when benefits reset in each new plan year.[47]

Evidence from value-based health plan design has focused primarily on chronic disease medications with generic competitors, but this approach could also be used to offer specialty drugs with very high clinical benefit to patients with less out-of-pocket obligation. Conceptually, it would be reasonable to steer patients to the most effective option within a specialty class (for example, the best tumor necrosis factor inhibitor for rheumatoid arthritis). Practically, physicians and

possibly patients will voice concerns about such an approach because of the clinical differences among products. Placing such coverage policies within the context of pragmatic trials or within Medicare demonstration projects may be one approach to allay concerns about preferential treatment within specialty drug classes.

LIMIT OUT-OF-POCKET SPENDING IN PART D

Medicare Part D does not currently have an annual out-of-pocket spending maximum for outpatient prescription drugs; this is true in both stand-alone drug plans and Medicare Advantage plans. Policy makers could place a limit on out-of-pocket prescription drug spending in Part D by removing the 5 percent coinsurance payment from the catastrophic phase of the benefit and limiting enrollees' annual cost sharing to the total out-of-pocket spending amount that currently triggers catastrophic coverage ($4,950 in 2017). In 2015, 3.6 million Medicare Part D enrollees had drug spending above the catastrophic threshold, with one million of these enrollees having no low-income subsidy to minimize out-of-pocket spending.[41]

A key challenge to this proposal is that pharmaceutical companies might respond by simply raising drug prices, because patients would not be price-sensitive after reaching the catastrophic coverage phase. Such tendencies could be mitigated, however, if Part D plans had a stronger financial incentive to negotiate larger rebates for higher-price drugs and to take more steps to manage the use of these drugs by their enrollees. Providing plans with such incentives could produce savings for enrollees, Medicare, and the plans themselves. For example, plans could be given greater financial responsibility for Part D spending in the catastrophic coverage phase (currently, plans are required to pay only 15 percent in this phase, compared to 75 percent in the initial coverage phase). A similar proposal has been suggested by the Medicare Payment Advisory Commission.[45]

Capping Part D spending would likely raise premiums across all beneficiaries, as current beneficiary spending in the catastrophic phase would need to be incorporated into program costs and redistributed across all insured people. In 2014, 3.6 million Part D beneficiaries reached catastrophic spending (out of 41 million beneficiaries in the Part D program), a dramatic increase from prior years.[44] Up-to-date estimates of beneficiaries' spending in catastrophic coverage and the possible impact on premiums are needed to determine whether such increases will be palatable to beneficiaries and policy makers.

Conclusion

We have provided an overview of key affordability challenges for patients needing high-cost specialty outpatient prescription medications. We have excluded specific discussion of drugs offered under Medicare Part B and commercial inpatient or outpatient medical coverage. However, some concerns noted regarding the increasing use of high deductibles and coinsurance would also apply to physician-administered medications.

We have discussed several proposals for limiting out-of-pocket spending for patients covered under commercial insurance and Medicare Part D. Data do not currently exist to determine empirically which of these options would provide the greatest net benefit to patients and payers. However, there may be political support for several proposed options, including removing catastrophic coinsurance on Medicare Part D and passing through estimated rebates at the point of sale.

In November 2017 the National Academies of Sciences, Engineering, and Medicine advanced similar recommendations targeting the affordability of medicines,[48] and CMS released a request for information for policy approaches for applying rebates and price concessions to drug prices at the point of sale in Medicare.[49] These are promising steps toward identifying the feasibility and impact of such a policy change.

Policies that provide patients with pre-deductible access to chronically used drugs or those that prevent increased medical spending may help avoid disruptions in ongoing disease management. This type of benefit design could be applied to both Medicare and commercial plans. More complex policies that include consideration of value in establishing cost sharing and coverage are more challenging to implement but may constitute a more promising long-term strategy. Evidence of their impact is sorely needed.

It will be important to monitor the extent to which our proposed solutions result in higher prices for payers, enrollees/beneficiaries, and society. Stakeholders should explore these options to determine the impact of their implementation on per member per month premium increases and whether they have spillover effects on other components of health spending as a result of potentially improved uptake of and adherence to prescribed drugs.

Our proposed solutions primarily focus on reducing patients' out-of-pocket spending through benefit design changes. These solutions do not address prescription drug affordability challenges for patients who lack health insurance coverage entirely or non–cost related drug access restrictions faced by Medicaid patients. These solutions also do not target the underlying prices of drugs, which are directly connected to affordability for patients who are required to pay a percentage of a drug's list price. Underlying drug prices also affect total insurer spending (which affects premiums for all insured people). However, these proposed options offer possible steps toward ensuring greater affordability for some insured patients who need costly medications.

Notes

1. Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group. National health expenditures by type of service and source of funds: calendar years 1960–2016 [Internet]. Baltimore (MD): CMS; 2016 [cited 2018 Jan 25]. Available from: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html

2. Express Scripts Lab. 2015 drug trend report. St. Louis (MO): Express Scripts; 2016 April.

3. Dusetzina SB. Share of specialty drugs in commercial plans nearly quadrupled, 2003–14. Health Aff (Millwood). 2016;35(7):1241–6.

4. Centers for Medicaid and Medicare Services. Announcement of calendar year (CY) 2018 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter and request for information 2017 [Internet]. Baltimore (MD): CMS; 2017 Apr 3 [cited 2018 Jan 22]. Available from: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf

5. Pew Charitable Trusts. Specialty drugs and health care costs [Internet]. Philadelphia (PA): Pew Charitable Trusts; 2016 Dec [cited 2018 Jan 22]. Available from: http://www.pewtrusts.org/~/media/assets/2016/12/specialty_drugs_and_health_care_costs.pdf

6. Jung JK, Feldman R, Cheong C, Du P, Leslie D. Coverage for hepatitis C drugs in Medicare Part D. Am J Managed Care. 2016;22(6 Spec No.):SP220-6.

7. Dusetzina SB, Keating NL. Mind the gap: why closing the doughnut hole is insufficient for increasing Medicare beneficiary access to oral chemotherapy. J Clin Oncol. 2016;34(4):375-80.

8. Yazdany J, Dudley RA, Chen R, Lin GA, Tseng CW. Coverage for high-cost specialty drugs for rheumatoid arthritis in Medicare Part D. Arthritis Rheumatol. 2015;67(6):1474-80.

9. Polinski JM, Mohr PE, Johnson L. Impact of Medicare Part D on access to and cost sharing for specialty biologic medications for beneficiaries with rheumatoid arthritis. Arthritis Rheum. 2009;61(6):745-54.

10. Doshi JA, Hu T, Li P, Pettit AR, Yu X, Blum M. Specialty tier-level cost sharing and biologic agent use in the Medicare Part D initial coverage period among beneficiaries with rheumatoid arthritis. Arthritis Care Res. 2016;68(11):1624–30.

11. Claxton G, Rae M, Long M, Damico A, Whitmore H, Foster G. Health benefits in 2017: stable coverage, workers faced considerable variation in costs. Health Aff (Millwood). 2017;36(10):1838–47.

12. Claxton G, Levitt L, Long M, Blumenkranz E. Increases in cost-sharing payments have far outpaced wage growth 2017. Peterson-Kaiser Health System Tracker [serial on the Internet]. 2017 Oct 4 [cited 2018 Jan 22]. Available from: https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/#item-start

13. National Cancer Institute. Financial Toxicity and Cancer Treatment (PDQ®)—Health Professional Version [Internet]. Bethesda (MD): NCI; 2017 May 3 [cited 2018 Jan 22]. Available from: https://www.cancer.gov/about-cancer/managing-care/track-care-costs/financial-toxicity-hp-pdq

14. Streeter SB, Schwartzberg L, Husain N, Johnsrud M. Patient and plan characteristics affecting abandonment of oral oncolytic prescriptions. J Oncol Practice. 2011;7(3 Suppl):46s–51s.

15. Winn AN, Keating NL, Dusetzina SB. Factors associated with tyrosine kinase inhibitor initiation and adherence among Medicare beneficiaries with chronic myeloid leukemia. J Clin Oncol. 2016;34(36):4323–8.

16. Neuner JM, Kamaraju S, Charlson JA, Wozniak EM, Smith EC, Biggers A, et al. The introduction of generic aromatase inhibitors and treatment adherence among Medicare D enrollees. J Natl Cancer Inst. 2015;107(8).

17. Zhang Y, Lave JR, Donohue JM, Fischer MA, Chernew ME, Newhouse JP. The impact of Medicare Part D on medication adherence among older adults enrolled in Medicare-Advantage products. Medical Care. 2010;48(5):409–17.

18. Solomon MD, Goldman DP, Joyce GF, Escarce JJ. Cost sharing and the initiation of drug therapy for the chronically ill. Arch Internal Med. 2009;169(8):740–8.

19. Shankaran V, Ramsey S. Addressing the financial burden of cancer treatment: from copay to can't pay. JAMA Oncol. 2015;1(3):273–4.

20. Romley J, Goldman D, Eber M, Dastani H, Kim E, Raparla S. Cost-sharing and initiation of disease-modifying therapy for multiple sclerosis. Am J Managed Care. 2012;18(8):460–4.

21. Kaisaeng N, Harpe SE, Carroll NV. Out-of-pocket costs and oral cancer medication discontinuation in the elderly. J Managed Care Spec Pharm. 2014;20(7):669–75.

22. Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. JAMA. 2007;298(1):61–9.

23. Ramsey SD, Bansal A, Fedorenko CR, Blough DK, Overstreet KA, Shankaran V, et al. Financial insolvency as a risk factor for early mortality among patients with cancer. J Clin Oncol. 2016;34(9):980–6.

24. Olszewski AJ, Dusetzina SB, Eaton CB, Davidoff AJ, Trivedi AN. Subsidies for oral chemotherapy and use of immunomodulatory drugs among Medicare beneficiaries with myeloma.J Clin Oncol. 2017;35(29):3306–14.

25. Fischer MA, Choudhry NK, Brill G, Avorn J, Schneeweiss S, Hutchins D, et al. Trouble getting started: predictors of primary medication nonadherence. Am J Med. 2011;124(11):1081 e9–22.

26. Dusetzina SB, Winn AN, Abel GA, Huskamp HA, Keating NL. Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. J Clin Oncol. 2014;32(4):306–11.

27. Doshi JA, Li P, Huo H, Pettit AR, Kumar R, Weiss BM, et al. High cost sharing and specialty drug initiation under Medicare Part D: a case study in patients with newly diagnosed chronic myeloid leukemia. Am J Managed Care. 2016;22(4 Suppl):s78–86.

28. Chen S, Levin RA, Gartner JA. Medication adherence and enrollment in a consumer-driven health plan. Am J Managed Care. 2010;16(2):e43–50.

29. Fronstin P, Sepulveda MJ, Roebuck MC. Medication utilization and adherence in a health savings account–eligible plan. Am J Managed Care. 2013;19(12):e400–7.

30. Fronstin P, Sepulveda MJ, Roebuck MC. Consumer-directed health plans reduce the long-term use of outpatient physician visits and prescription drugs. Health Aff (Millwood). 2013;32(6):1126–34.

31. Greene J, Hibbard J, Murray JF, Teutsch SM, Berger ML. The impact of consumer-directed health plans on prescription drug use. Health Aff (Millwood). 2008;27(4):1111–9.

32. Nair KV, Park J, Wolfe P, Saseen JJ, Allen RR, Ganguly R. Consumer-driven health plans: impact on utilization and expenditures for chronic disease sufferers. J Occup Environ Med. 2009;51(5):594–603.

33. Pauly MV. Economics of moral hazard. Am Econ Rev. 1968;58(3):531–7.

34. Henry J. Kaiser Family Foundation, Health Research and Educational Trust. Employer health benefits: 2016 annual survey. Menlo Park (CA): KFF; 2016.

35. HealthCare.gov. Out-of-pocket maximum/limit [Internet]. Washington (DC): Department of Health and Human Services; 2017 [cited 2018 Jan 22]. Available from: https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/

36. Rae M, Levitt L, Claxton G, Cox C, Long M. Patient cost-sharing in Marketplace plans, 2016 [Internet]. Menlo Park (CA): Henry J. Kaiser Family Foundation; 2015 Nov 13 [cited 2018 Jan 22]. Available from: https://www.kff.org/health-costs/issue-brief/patient-cost-sharing-in-marketplace-plans-2016/

37. Cox C. What are recent trends and characteristics of workers with high drug spending? Peterson-Kaiser Health System Tracker [serial on the Internet]. [Updated 2016 Oct 27; cited 2017 Jul 31]. Available from: http://www.healthsystemtracker.org/chart-collection/recent-trends-characteristics-workers-high-drug-spending/?_sf_s=recent#item-start

38. Henry J. Kaiser Family Foundation. The Medicare Part D prescription drug benefit [Internet]. Menlo Park (CA): KFF; 2017 Oct 2 [cited 2018 Jan 25]. Available from: https://www.kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/

39. Medicare Payment Advisory Commission. Report to the Congress: Medicare and the health care delivery system [Internet]. Washington (DC): MedPAC; 2017. Chapter 10, Provider consolidation: the role of Medicare policy; [cited 2018 Jan 22]. Available from: http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0

40. Hoadley J, Cubanski J, Neuman T. It pays to shop: variation in out-of-pocket costs for Medicare Part D enrollees in 2016 [Internet]. Menlo Park (CA): Henry J. Kaiser Family Foundation; 2015 Dec 2 [cited 2018 Jan 22]. Available from: http://www.kff.org/report-section/it-pays-to-shop-variation-in-out-of-pocket-costs-for-medicare-part-d-enrollees-in-2016-findings/

41. Cubanski J, Neuman T, Orgera K, Damico A. No Limit: Medicare Part D enrollees exposed to high out-of-pocket drug costs without a hard cap on spending [Internet]. Menlo Park (CA): Henry J. Kaiser Family Foundation; 2017 Nov 7 [cited 2018 Jan 22]. Available from: https://www.kff.org/report-section/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending-issue-brief/

42. Medicare Payment Advisory Commission. Report to the Congress: Medicare and the health care delivery system [Internet]. Washington (DC): MedPAC; 2016. Chapter 6, Improving Medicare Part D; [cited 2018 Jan 22]. Available from: http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0

43. Dusetzina SB, Conti RM, Yu NL, Bach PB. Association of prescription drug price rebates in Medicare Part D with patient out-of-pocket and federal spending. JAMA Internal Med. 2017;177(8):1185–8.

44. Department of Health and Human Services, Office of Inspector General. High-price drugs are increasing federal payments for Medicare Part D catastrophic coverage [Internet]. Washington (DC): HHS; 2017 Jan [cited 2018 Jan 22]. Available from: https://oig.hhs.gov/oei/reports/oei-02-16-00270.pdf

45. Medicare Payment Advisory Commission. Report to the Congress: Medicare payment policy [Internet]. Washington (DC): MedPAC; 2017 Mar. Chapter 14, Status report on the Medicare prescription drug program (Part D) [cited 2018 Jan 22]. Available from: http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf?sfvrsn=0

46. CMS.gov. Medicare Part D—Direct and Indirect Renumeration (DIR) [Internet]. Baltimore (MD): Centers for Medicare and Medicaid Services; 2017 Jan 19 [cited 2018 Jan 22]. Available from: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/ 2017-01-19-2.html

47. Fendrick AM, Chernew ME. Precision benefit design-using "smarter" deductibles to better engage consumers and mitigate cost-related nonadherence. JAMA Internal Med. 2017;177(3):368–70.

48. National Academies of Sciences, Engineering, and Medicine. Making medicines affordable: a national imperative. Washington (DC): National Academies Press; 2017.

49. CMS.gov. CMS proposes policy changes and updates for Medicare Advantage and the prescription drug benefit program for contract year 2019 (CMS-4182-P) [Internet]. Baltimore (MD): Centers for Medicare and Medicaid Services; 2017 Nov 16 [cited 2018 Jan 24]. Available from: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-16.html

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