THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700
Philadelphia, PA 19103-7077
215.575.9050 Phone
215.575.4939 Fax

901 E Street NW, 10th Floor
Washington, DC 20004
202.552.2000 Phone
202.552.2299 Fax
www.pewtrusts.org

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Submitted electronically via Regulations.gov

Department of Health and Human Services
Attention: RIN 0991-ZA49
200 Independence Ave. SW, Room 600E
Washington, DC 20201

Re: RIN 0991-ZA49; HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

The Pew Charitable Trusts (Pew) is pleased to offer comments on the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs Request for Information (RFI). Pew is an independent, nonpartisan research and public policy organization dedicated to serving the American public. Our drug spending research initiative is focused on identifying policies that would allow public programs to better manage spending on pharmaceuticals while ensuring that patients have access to the drugs that they need.

Pew commends the Department of Health and Human Services (HHS) for its commitment to addressing drug spending and drug costs. Our response to the RFI is presented thematically with references to direct questions from the RFI presented in sidebars. Our comments address the following topics:

- **Federal Program Incentives** – Unlike other government programs, Medicare Part B does not have the correct incentives to reduce drug spending.
- **Drug Pricing Structures and Incentives** – Proposals to reform the Medicare Part B Competitive Acquisition Program and negotiate additional discounts could reduce drug spending, while proposals focusing on price transparency, value-based purchasing, indication-based pricing, long-term financing, and the protected classes may be unlikely to reduce – and could even increase – drug spending.
- **Price Reporting Requirements and Incentive Structures** – Removing the cap on Medicaid rebates could discourage drug price spikes. The growth of innovative drug pricing contract mechanisms suggests that price reporting requirements are not a categorical barrier to innovative drug pricing contract mechanisms, and any changes to these requirements should be narrowly-tailored to specific examples of money-saving arrangements to avoid undermining existing protections for federal healthcare programs.
- **Cost-Shifting and Cross-Subsidization** – Economic theory and empirical analyses do not support the proposition that drug discounts for some purchasers raise prices to other purchasers for

brand drugs; any effect on generic drugs does not appear to have materially increased drug spending.

- **Generic Drug Pricing and Development** – Requiring provision of drug samples for generic development as a condition of Medicare and Medicaid participation could increase generic competition. Existing government drug spending is unlikely to be negatively impacting the generic drug market.
- **Pharmacy Benefit Managers and Rebates** – Pharmacy Benefit Managers and drug rebates likely reduce drug spending, and proposed reforms could increase drug spending. Antitrust regulation and enforcement may be important to promote a competitive pharmaceutical marketplace and reduce spending.
- **340B Drug Pricing Program** – 340B discounts are unlikely to be causing drug price increases and may actually discourage price increases. Reducing the size of the 340B program would be unlikely to lower drug spending and would redistribute existing hospital discounts to drug manufacturers.
- **Patient Cost-Sharing** – Patient cost-sharing is a function of insurance design, not drug prices, and insurers that reduce patient cost-sharing should be empowered to more rigorously manage drug utilization with appropriate clinical safeguards.

Pew appreciates the opportunity to comment on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. The Blueprint and this comment period are important steps to reduce drug spending, and we commend the Administration for its attention to drug costs. We would be happy to discuss any of our comments in more detail.

Federal Program Incentives

The RFI solicits comment on whether HHS programs have the correct incentives to obtain affordable drug prices. We address each of the key HHS drug purchasing programs below.

> Do HHS programs contain the correct incentives to obtain affordable prices on safe and effective drugs?

The Medicare Part A program encourages hospitals to use the cheapest drug that is clinically effective, reducing costs through both utilization management and incentives to obtain the lowest price. The bundling methodology[1] used in Part A may reduce costs if applied to other federal health programs.

The Medicare Part B program encourages higher, rather than lower, costs for single-source drugs. Because physicians are fully reimbursed for the cost of a drug plus a 6% payment,[2] physicians see higher revenue from more expensive drugs. This may encourage physicians to use not only a higher volume of drugs, but also more expensive drugs.[3] However, multi-source drugs that are bundled into a single

[1] 42 U.S.C. § 1395f

[2] 42 U.S.C. § 1395w–3a

[3] "Financial considerations may also play a role in providers' choice of drugs. Concern has been expressed by some researchers and stakeholders that the 6 percent add-on to ASP creates an incentive to use higher priced drugs when cheaper therapeutic alternatives are available." (internal citations omitted) Medicare Payment Advisory

reimbursement code actually encourage lower prices.[4] Because physicians are reimbursed on the average price of all drugs in the code, individual manufacturers compete to reduce their price so that it is below the average, encouraging physicians to use that product to obtain greater revenue while simultaneously reducing the average price for the entire code, generating a downward trend. This bundling method has greater potential to reduce costs than the coding structure for single-source drugs, which tends to increase costs.

The Medicare Part D program design has been successful in generating price concessions from manufacturers. Pharmacy Benefit Managers (PBMs) have been very effective managing cost growth through rebates, such that premiums actually fell in 2018.[5] Because PBMs and plans are required to pass all discounts back to Medicare and beneficiaries through lower premiums, Part D prevents supply chain entities from withholding discounts and instead encourages competition for beneficiary volume on premiums.[6] This incentive structure, combined with effective care quality standards, encourages cost reductions through both appropriate utilization management and negotiated discounts.[7]

The Medicaid program is effective at limiting the impact of drug price increases, but it may not have the appropriate tools to negotiate discounts on drugs with high-list prices, as Medicaid formularies are required to include all drugs from manufacturers participating in the Medicaid Drug Rebate Program.[8] Some states do not engage in any supplemental rebate negotiation, while others only negotiate as a

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Committee (MedPAC), "June 2016 Report to Congress: Medicare and the Healthcare Delivery System," 2016, http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.

[4] "The current ASP payment system spurs price competition among generic drugs and their associated brand products by assigning these products to a single billing code." MedPAC, "Medicare Part B Drug Payment Policy Issues," 2017, http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0.

[5] In 2017, the base beneficiary premium was $35.63; in 2018, $35.02. Centers for Medicare and Medicaid Services (CMS), "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information," July 29, 2016, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2017.pdf, and CMS, "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information," July 31, 2017, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2018.pdf.

[6] Discussed in more detail in the section Pharmacy Benefit Managers and Rebates. "This bid is based on the sponsor's estimate of its anticipated drug costs, as well as its administrative costs, which include nonpharmacy expenses and expected profit. Expected profit, also known as the gain/loss margin, is the additional revenue the sponsor requires above the amount needed to cover drugs costs and other expenses." HHS OIG, "Medicare Part D Reconciliation Payments for 2006-2007," OEI-02-08-00460, Sept. 2009, https://oig.hhs.gov/oei/reports/oei-02-08-00460.pdf.

[7] "Compared to the 2016 report, actual premiums, government contributions, and benefit payments for 2017 were all significantly lower than projected primarily for three reasons: (i) the drug rebates were higher than previously assumed; (ii) the actual drug trend was lower due to a decline in hepatitis C drug spending; and (iii) the 2016 reinsurance reconciliation amounts paid in 2017 were lower than projected in the 2016 report." "2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," pp. 101-102, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.

[8] 42 U.S.C. § 1396r-8(d)(1)

single state, which may limit their power to obtain price concessions.[9] HHS could support states by negotiating discounts on behalf of all states for high-cost drugs.

Drug Pricing Structures and Incentives

The RFI addresses several different pricing structures and incentives that may affect drug prices, with particular attention to strategies that may reduce spending in Medicare Part B; other key strategies include price transparency, value-based purchasing, indication-based payments, long-term financing, and the protected classes. In this section, Pew addresses how these proposals may or may not affect drug prices. Pew separately addresses the relationship of these proposals to government price reporting obligations and other enforcement concerns in the next section, titled Price Reporting Requirements and Incentive Structures.

Medicare Part B Competitive Acquisition Program, Negotiation, and Moving Drugs to Part D

The RFI solicits comments on a variety of proposals to reform the Medicare Part B program. Pew commends the Administration for its attention to the Part B program, where the current structure incents the use of both more drugs and more expensive drugs, all without any of the standard tools used by private and other government payers to manage utilization and spending. While we address the specific proposals outlined in the RFI, we first address other policy solutions that may be both easier to implement and more effective in reducing spending.

> What changes would vendors and providers need to see relative to the 2007-2008 implementation of this program [Competitive Acquisition Program] in order to successfully participate in the program?
>
> Which drugs or classes of drugs would be good candidates for moving from Part B to Part D?

New, high-cost drugs are the primary driver of rising drug spending.[10] Many of the costliest products must be administered in the physician's office or clinic, including drugs to treat cancer, rheumatoid arthritis and other complex conditions. Medicare covers these therapies drugs through the Part B program, separate from the Part D outpatient prescription drug benefit. Medicare Part B spending on drugs has risen more than nine percent annually in recent years,[11] and this trend is expected to accelerate.

The key challenge with reducing Medicare Part B spending originates in the nature of its payment structure – the program does not directly pay for drugs, but instead reimburses providers for their costs under a "buy-and-bill" model. This model may create misaligned incentives because providers receive

[9] CMS, "Medicaid Pharmacy Supplemental Rebate Agreements (SRAs)," March 2018, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf.
[10] IQVIA, "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," April 2018.
[11] MedPAC, "A Data Book: Health Care Spending and the Medicare Program," 2017, http://www.medpac.gov/docs/default-source/data-book/jun17_databooksec10_sec.pdf?sfvrsn=0.

higher payments if they use more costly products, regardless of the relative value of the drug.[12, 13] Similarly, providers may find it more profitable to use higher volumes of drugs or prefer intravenous rather than oral cancer therapies, even if not clinically superior.[14] There has been limited research on the impact of Medicare Part B reimbursement policy on prescribing, but there is some evidence suggesting that these incentives affect provider behavior. For example, a study by the HHS Office of the Inspector General (OIG) reported movement away from cheaper drugs and toward higher-priced options among therapeutically similar prostate cancer drugs when they began to be reimbursed based on 106 percent of their own Average Sales Prices.[15] Similarly, a study of utilization of five lung cancer drugs found a modest increase in the use of the most expensive therapy when Medicare adopted its current reimbursement policy.[16]

Medicare Part B lacks the tools used by the Part D drug program and in the commercial sector to manage spending. For example, Medicare does not employ a formulary in Part B, nor does it leverage its purchasing power to negotiate prices with manufacturers. Current Part B payment policy can also discourage manufacturers from lowering prices.

One approach to reduce spending in Part B is to reduce payments to providers. Reducing payments to providers is challenging, however, because payments lower than the cost of the drug would leave physicians "under water" – i.e. reimbursed at less than their cost of acquisition – discouraging participation in the Medicare program. Another approach would be to use a third-party entity to negotiate discounted up-front drug prices. Medicare could establish a system for providers to purchase drugs at this discounted price and reimburse providers to reflect the lower acquisition cost. However, the provider would then be tasked with maintaining a separate drug inventory for Medicare beneficiaries (to avoid diverting Medicare discounts to other payers). Each of these options would introduce some burden for providers, hampering implementation feasibility.

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[12] "Financial considerations may also play a role in providers' choice of drugs. Concern has been expressed by some researchers and stakeholders that the 6 percent add-on to ASP creates an incentive to use higher priced drugs when cheaper therapeutic alternatives are available." (internal citations omitted) MedPAC, "June 2016 Report to Congress: Medicare and the Healthcare Delivery System," 2016, http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.

[13] For a discussion of various incentives under the Part B reimbursement structure and the evidence supporting them, including a discussion of how manufacturers may be encouraged to establish higher list prices, *see* Polite, B., Conti, RM., Ward, JC. "Reform of the buy-and-bill system for outpatient chemotherapy care is inevitable: Perspectives from an economist, a realpolitik, and an oncologist." American Society of Clinical Oncology educational book/ASCO. American Society of Clinical Oncology. Meeting. NIH Public Access, 2015.

[14] "The oncologists who provide care to cancer patients face financial incentives to administer intravenous anticancer drugs … Medical oncology practices derive more than 50 percent of their revenues from drugs." Howard, DH., et al. "Pricing in the market for anticancer drugs." Journal of Economic Perspectives 29.1 (2015): 139-62 (internal citations omitted).

[15] HHS Office of the Inspector General (OIG), "Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B" (2012), http://oig.hhs.gov/oei/reports/oei-12-12-00210.pdf.

[16] Jacobson, M., et al. "How Medicare's payment cuts for cancer chemotherapy drugs changed patterns of treatment." Health Affairs 29.7 (2010): 1391-1399.

Reduced drug spending could be more easily achieved if drug manufacturers paid offsetting discounts to the Medicare program for Part B drugs used by Medicare beneficiaries. This would be similar to the systems used by private payers, Medicaid, and the Medicare Part D program. To provide Medicare leverage in negotiating discounts with manufacturers, when multiple therapeutically similar drugs are available, Medicare Part B could provide reimbursement incentives for physicians to select the drug with the lowest net cost (subject to clinical appropriateness). One study found that add-on incentive payments to use a lower-cost drug to treat macular degeneration would save $18 billion for Medicare Part B and $5 billion in patient cost-sharing over ten years.[17] This approach would eliminate the need to subject physicians to the increased financial and administrative burdens associated with reduced direct reimbursement strategies. However, directing utilization to more cost-effective therapies would also require the use of one or more utilization management tools, such as a formulary, prior authorization, or step therapy. While utilization management would introduce some administrative burden for providers, they are likely accustomed to utilization management for their privately-insured patients.

The existing Part B Competitive Acquisition Program (CAP) authority[18] may serve as a framework to establish such a system. The CAP operated from June 2006 to December 2008. One goal of the program was to address misaligned financial incentives have for prescribing drugs in Medicare Part B. Under the program, Medicare paid a vendor to supply Part B drugs to physicians who chose to enroll in the program instead of paying the physicians directly for the drugs they administered. As discussed in the Medicare Payment Advisory Commission's (MedPAC's) June 2016 report, the CAP was viewed as unsuccessful largely because physician enrollment was low and because the vendor had little leverage to negotiate discounts, as the CAP vendor was required to cover all biologics and single-source drugs and was not permitted to create a formulary.[19] Although the CAP program faced challenges, the concept underlying the program—to create a voluntary alternative to the buy-and-bill system using private vendors to negotiate favorable prices and eliminate financial incentives for physicians to prescribe Part B drugs—still has appeal.

While the existing CAP legislation addresses a system where contractors are involved in the physical transfer of drugs from manufacturers to physicians, the Secretary should evaluate whether the current authority allows the contractors to simply negotiate discounts with manufacturers and handle the payment to physicians while still allowing physicians to purchase drugs through their standard acquisition channels. In this scenario, contractors would present discounted price bids for specified drugs under the CAP to Medicare. After selecting appropriate contractors, providers would choose to enroll in the program under the existing CAP terms, where providers agree to use the CAP's drug selections for all therapeutic classes included in the CAP, but instead of being shipped the drugs from the contractor, the physician would use her existing drug inventory to treat Medicare beneficiaries. The contractor would fully reimburse the physician at the standard cost of acquisition, Medicare would pay

[17] Hutton, D., et al. "Switching to less expensive blindness drug could save Medicare Part B $18 billion over a ten-year period." Health Affairs 33.6 (2014): 931-939.
[18] 42 U.S.C. § 1395w–3b
[19] MedPAC, "Medicare Part B drug and oncology payment policy issues," 2016, http://www.medpac.gov/docs/default-source/reports/chapter-5-medicare-part-b-drug-and-oncology-payment-policy-issues-june-2016-report-.pdf?sfvrsn=0.

the contractor the discounted payment amount, and the contractor would collect the difference from the manufacturer as a discount payment.

A critical requirement for a CAP program to generate savings is that the contractor would need to be able to develop a formulary and employ certain utilization management tools common in Part D and the commercial sector, such as prior authorization and step therapy. A successful program would also need to include utilization management incentives for participating physicians, such as increased reimbursement for preferred drugs and decreased reimbursement for non-preferred drugs (subject to clinical appropriateness). These tools would provide vendors leverage in negotiating discounts with manufacturers. Furthermore, such a program would likely need tools to increase provider participation. These could include shared savings opportunities or other financial incentives. The Secretary should evaluate whether current authority allows the use of such utilization management tools and provider incentives.

Negotiating discounts under the CAP may also address one of the challenges in moving Part B drugs to Medicare Part D. The Medicare Part D statute generally prohibits Part D plans from reimbursing for drugs at locations other than a pharmacy,[20] which complicates the ability to leverage the existing Part D structure without statutory changes. If a CAP contractor is associated with a Part D plan, however, the contractor may be able to leverage discounts across its Part B and Part D portfolios. For example, consider a manufacturer with a Part B drug that does not have any therapeutic competition as well as Part D drug with significant competition (e.g., a hepatitis C treatment or an antidepressant). The contractor could require the manufacturer to offer discounts on its Part B product in order for the contractor to prefer the Part D product against therapeutically-similar products. This would allow the contractor to leverage formulary competition in the Part D space to obtain price concessions on Part B drugs without formally moving a Part B drug into the Part D program and triggering existing pharmacy payment barriers. The Medicare Advantage program, which administers both Part B and Part D benefits, may serve as a model for this coordination. The Secretary should consider providing guidance to Medicare Advantage plans encouraging this type of negotiation and allowing Medicare Advantage plans to engage in utilization management for Part B drugs in support of negotiating price concessions.

The Drug Value Program (DVP) is another approach that could address the deficiencies of the buy-and-bill approach offer savings to the federal government, providers and beneficiaries by creating competition and expanding choice. The DVP was proposed by MedPAC in 2017 and includes critical elements for a successful reimbursement system, many of which are described above in the context of a modified CAP program.[21] Additional elements of a DVP as proposed include binding arbitration as a tool to facilitate vendor and manufacturer price negotiations for high-priced drugs without close substitutes and shared savings for providers and beneficiaries.

[20] 42 C.F.R. § 423.100

[21] MedPAC, "Medicare Part B Drug Payment Policy Issues," 2017, http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0.

The RFI also solicits comments on various approaches to discourage price increases among Part B drugs, including assigning designated Healthcare Common Procedure Coding System (HCPCS) codes to drugs that commit to prices over a period. In general, Part B drugs take smaller price increases than other drugs,[22] suggesting that policies to reduce price increases may not result in significant cost savings. The reimbursement structure of the Part B program may itself discourage price increases; reimbursement is based on the Average Sales Price (ASP) for a drug two quarters previous,[23] meaning that physicians may face below-cost reimbursement if the manufacturer takes a large price increase.

Indeed, the Part B program already has an effective mechanism to encourage manufacturers to reduce their prices – grouping multiple drugs into the same reimbursement code.[24] Generally used for generic drugs, grouping drugs from multiple manufacturers into the same reimbursement code and then reimbursing based on a volume-weighted average of the prices in the group encourages manufacturers to reduce their prices so that physicians realize higher revenue from selecting the lowest-cost drug in the group.[25] If Medicare were to group clinically similar brand drugs into the same reimbursement code, this would create an incentive for manufacturers to lower, rather than raise, their prices. There is immediate potential for savings from an approach that groups all biosimilars and their shared reference product into a single billing code, as MedPAC recommended.[26]

The Healthcare Common Procedure Coding System (HCPCS) codes for new Part B drugs are not typically assigned until after they are commercially available. Should they be available immediately at launch for new drugs from manufacturers committing to a price over a particular lookback period?

What should CMS consider doing, under current authorities, to create incentives for Part B drugs committing to a price over a particular lookback period? How long should the lookback period be? How could these incentives affect the behavior of manufacturers and purchasers? What are the operational concerns to implementing them? Are there other incentives that could be created to reward manufacturers of drugs that have not taken a price increase during a particular lookback period?

[22] From 2016-2017, average price growth for the top 20 highest-expenditure Part B drugs was 3.7 percent (from 2010-2016, average annual growth was 4.6%); for all brand drugs, average price growth for the period was 6.9 percent (below the previous annual price growth of 13.5% in 2014, 11.9% in 2015, and 9% in 2016). MedPAC, "Medicare Part B Drug Payment Policy Issues," 2017, http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0, and IQVIA, "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," April 2018, https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

[23] HHS OIG, "Average Sales Prices: Manufacturer Reporting and CMS Oversight," OEI-03-08-00480, Feb. 2010, https://oig.hhs.gov/oei/reports/oei-03-08-00480.pdf.

[24] HHS OIG, "Medicare Payments for Newly Available Generic Drugs," OEI-03-09-00510, Jan. 2011, https://oig.hhs.gov/oei/reports/oei-03-09-00510.pdf.

[25] "The current ASP payment system spurs price competition among generic drugs and their associated brand products by assigning these products to a single billing code." MedPAC, "Medicare Part B Drug Payment Policy Issues," 2017, http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0.

[26] "Grouping the reference biologic and its biosimilars together under one billing code and paying all of them the same rate would be expected to generate greater price competition than using two separate codes for these

Price Transparency

> What steps can be taken to improve price transparency in Medicare, Medicaid, and other forms of health coverage, so that consumers can seek value when choosing and using their benefits?

Transparency of net prices after rebates or other discounts may be of limited use for consumers and may actually lead to drug price increases. For consumers, the cost-sharing amount paid is established by their insurer, whether a private insurer or through the Medicare or Medicaid program. Even when cost-sharing payments are calculated as a percentage of a drug's list price (co-insurance), the choice to use co-insurance is governed by the insurer, not the drug manufacturer. Because the net price of a drug is distinct from the price paid by the consumer, transparency of net prices is unlikely to affect consumer choices or spending.

Overall, net price transparency may actually increase drug prices by allowing drug manufacturers to tacitly engage in price fixing. The Federal Trade Commission warns that price transparency may "allow competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price, or increases the likelihood that they can coordinate on higher prices."[27] Empirical evidence supports this theory. In the early 1990's, the Danish Competition Council required the publication of privately negotiated discounts for ready-mixed concrete; following this publication, prices rose 15-20% within a year, which experts attribute to increased collusion among the oligopoly of producers.[28] In the brand drug market, where a limited number of manufacturers offer similar products within a therapeutic class, net price transparency may cause these manufacturers to collectively raise prices. The already occurs with drug list prices. For example, one study found that prices for older multiple sclerosis drugs have increased nearly in lockstep with newer, costlier therapies entering the market. List prices for first-generation therapies, originally costing $8,000 to $11,000, rose to about $60,000 per year by 2013.[29] Insulin therapies have similarly increased in lockstep,[30] leading to bipartisan Congressional inquiries.[31]

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products." MedPAC, "Medicare Part B Drug Payment Policy Issues," 2017, http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0.

[27] Koslov, TI, Jex, E. "Price transparency or TMI?," Federal Trade Commission, July 2, 2015, https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.

[28] Albæk, Svend, Peter Møllgaard, and Per B. Overgaard. "Government-assisted oligopoly coordination? A concrete case." The Journal of Industrial Economics 45.4 (1997): 429-443.

[29] Hartung, Daniel M., Dennis N. Bourdette, Sharia M. Ahmed, and Ruth H. Whitham. "The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: Too big to fail?." Neurology 84, no. 21 (2015): 2185-2192.

[30] Ramsey, L. "The prices for life-saving diabetes medications have increased again," Business Insider, May 15, 2017, http://www.businessinsider.com/insulin-prices-increased-in-2017-2017-5.

[31] U.S. Senate Special Committee on Aging, "Insulin Access and Affordability: The Rising Cost of Treatment," Hearing, May 8, 2018, https://www.aging.senate.gov/hearings/insulin-access-and-affordability-the-rising-cost-of-treatment. Congressional Caucus on Diabetes, "Insulin Pricing," https://diabetescaucus-degette.house.gov/insulin-pricing.

Value-Based Purchasing

Value-Based Purchasing (VBP), where manufacturers and payers agree to price a drug based on a measure of clinical value, could limit drug spending in certain markets but may actually increase drug spending in others. Evidence from other countries that have invested in VBP mechanisms indicates only limited financial savings.[32] This mixed utility, combined with significant implementation challenges, may explain the limited uptake of VBP among payers.

VBP would only be expected to reduce drug spending if payers are currently voluntarily paying above a drug's perceived value. Perceived value may be driven by an assessment of clinical value as well as other factors, such as costs of denying coverage (e.g., damage to company reputation, decrease in plan quality rating, loss of customers). In cases where payers are able to deny coverage of drugs, they would be expected to negotiate a price at or below the perceived value of the drug. For payers that are unable to deny or heavily restrict coverage of drugs, such as Medicare Part B, VBP may offer some savings relative to current spending. However, manufacturers would not be expected to offer VBP price concessions if the payer is required to cover the drug regardless of price.

What benefits would accrue to Medicare and Medicaid beneficiaries by allowing manufacturers to exclude from statutory price reporting programs discounts, rebates, or price guarantees included in value-based arrangements?

What regulatory changes would Medicaid Managed Care organizations find helpful in negotiating VBP supplemental rebates with manufacturers?

How would these changes affect Medicare or the 340B program?

When a drug market has some competition, agreeing to pay for drugs based on value may actually lead to increased drug spending. Consider the hepatitis C treatment market – the introduction of multiple brand competitors caused prices to fall 45-55% within only two years of release,[33] even though the drugs were generally cost-effective at launch prices.[34,35] If value or cost-effectiveness were used as a metric to pay for these drugs, spending would be significantly higher.

[32] Navarria, Andrea, et al. "Do the current performance-based schemes in Italy really work? 'Success fee:' a novel measure for cost-containment of drug expenditure." Value in Health 18.1 (2015): 131-136.
[33] Dan, C. "In Case You Missed It – 2016 Study Compared Hepatitis Treatment Costs," HHS Office of HIV/AIDS and Infectious Disease Policy, Jan. 3, 2017, https://www.hhs.gov/hepatitis/blog/2017/1/3/icymi-2016-study-compared-hepatitis-c-treatment-costs.html.
[34] Tice, J. A., et al. "The comparative clinical effectiveness and value of novel combination therapies for the treatment of patients with genotype 1 chronic hepatitis C infection: a technology assessment," Institute for Clinical and Economic Review, Jan. 30, 2015, http://ctaf.org/reports/newest-treatments-hepatitis-c-genotype-1.
[35] Chahal, Harinder S., et al. "Cost-effectiveness of early treatment of hepatitis C virus genotype 1 by stage of liver fibrosis in a US treatment-naive population." JAMA Intern Med. 176.1 (2016): 65-73.

The RFI specifically solicits information on what changes to federal price reporting requirements and the antikickback statute may engender increased adoption of VBP arrangements and how these changes may benefit Medicare and Medicaid beneficiaries. We discuss specific price reporting and antikickback concerns separately in this letter, but the development of VBP arrangements under current regulations suggests that these concerns are not a major barrier to VBP adoption.[36] The Centers for Medicare & Medicaid Services (CMS) could, however, clarify that best price does not include discounts under VBP arrangements with Medicaid Managed Care Organizations (MCOs) that are not Health Maintenance Organizations (HMOs). Currently, the best price implementing regulations listing transactions that must be included in best price parenthetically include MCOs as a subset of HMOs;[37] clarifying that non-HMO MCOs are excluded from best price may remove this concern as a potential barrier to VBP development.[38]

> Are there particular sections of the Social Security Act (e.g., the antikickback statute), or other statutes and regulations that can be revised to assist with manufacturers' and states' adoption of value-based arrangements? Please provide specific citations and an explanation of how these changes would assist states and manufacturers in participating in VBP arrangements.

More broadly, VBP arrangements with MCOs depend on how the state has structured its Medicaid drug benefit and whether MCOs individually have sufficient negotiating power to develop a VBP arrangement with manufacturers. To maximize negotiating power, a state may carve out some (e.g., high-cost drugs, orphan drugs) or all drugs from its MCO contracts in order to leverage its buying power for all Medicaid beneficiaries in negotiating discounts. Any attempt to encourage MCOs to directly negotiate VBPs with manufacturers must consider whether Medicaid negotiations for all MCO beneficiaries may yield greater cost-savings than individual MCO negotiations.

Medicare and Medicaid beneficiaries are unlikely to benefit directly from the adoption of VBP arrangements or the exclusion of VBP arrangements from federal price reporting requirements. If these arrangements generate substantial cost-savings, Medicare Part D beneficiaries may see reduced insurance premiums. If VBP discounts are included in the Medicaid Average Manufacturer Price (AMP) calculation and materially reduce AMP, their exclusion from AMP would cause AMP to increase, which may increase the rebates manufacturers pay to Medicaid programs. Conversely, excluding these discounts from best price may reduce manufacturer rebates to Medicaid programs.

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[36] Kaltenboeck, A., Bach, P. "Value-based pricing vs. outcomes-based contracting: Frequently asked questions," Drug Pricing Lab, Memorial Sloan Kettering, June 21, 2017, https://drugpricinglab.org/our-work/value-based-pricing-vs-outcomes-based-contracting/. ("Outcomes-based contracts have been announced in the United States for Repatha, Praluent, Entresto, Actonel, and Enbrel, among others. It seems unlikely that these contracts could be in the field and violating current Medicaid Best Price rules.")

[37] 42 C.F.R. § 447.505

[38] This would be consistent with existing Medicaid policy that supplemental rebates for drugs used by MCO enrollees do not trigger best price. CMS, "Medicaid Drug Rebate Program State Release No. 176: Value Based Purchase Arrangements and Impact on Medicaid," July 14, 2016, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-176.pdf.

Indication-Based Pricing

Indication-based pricing, where the same drug is priced differently based on clinical use, can likely be achieved through existing payer rebate structures, discussed below, similar to mechanisms used for value-based purchasing. Indication-based pricing may not reduce drug spending, however, if manufacturers choose to raise prices for high-value uses but do not reduce prices for lower-value uses.

Indication-based pricing would only yield cost-savings if manufacturers price drugs for a high-value clinical use but are still able to force payers and patients to pay this high-value price for a low-value use. Because of data limitations, payers may not be able to determine whether a patient is using a drug for a high- or low-value indication. This makes it challenging for payers to deny coverage for low-value uses. These data limitations would have to be resolved prior to implementation of any indication-based pricing arrangement, as manufacturers would be unwilling to reduce prices if insurers continue to pay the high-value price for all uses.

Should Medicare or Medicaid pay the same price for a drug regardless of the diagnosis for which it is being used?

How could indication-based pricing support value-based purchasing? What lessons could be learned from private health plans?

Are there unintended consequences of current low-cost drugs increasing in price due to their identification as high value?

For drugs that are currently priced for a low-value, high-volume use, enforceable[39] indication-based pricing may actually lead to higher drug spending. In this instance, manufacturers would raise the price for the uncommon, high-value use without concern that insurers would restrict access for the common, low-value use, which may increase overall drug spending.[40]

For drugs that are currently priced for a high-value use but may have utility in a lower-value treatment, manufacturers could use existing rebate mechanisms to offset costs for lower-value treatments. Manufacturers and payers, including Medicaid and Medicare Part D, could negotiate to determine appropriate net prices for lower-value treatments. Payers would be responsible for providing appropriate documentation of diagnoses in their rebate invoices. This approach is consistent with how manufacturers and payers can implement value-based purchasing arrangements, reducing the need for changes to existing pricing structures.

The RFI solicits comment on unintended consequences of current-low cost drugs increasing in price due to their identification as high-value. As a threshold matter, this practice underscores the problem of value-based approaches to pricing – paying for a drug's value may actually lead to higher drug spending, as the competitive price for the drug may be significantly lower than its value. Indication-based pricing mechanisms that reduce drug spending, such as rebates for new low-value uses of old high-cost drugs,

[39] If a patient with a high-value need can access the drug at the low-value price (such as through off-label prescribing), the manufacturer would not be able to effectively charge different prices.
[40] Chandra, A, Garthwaite, C. "The Economics of Indication-Based Drug Pricing," New England Journal of Medicine 377.2 (2017): 103-106.

could also be used to allow the manufacturer to increase the price of an older drug to the new high-value price, requiring payers to demonstrate that a particular claim was for the low-value use in order to receive a rebate to the previous low price. For these types of price increases, heightening the effect of the Medicaid inflation penalty may discourage manufacturers from raising prices significantly – eliminating the Medicaid inflation penalty cap, as discussed below, can discourage this behavior. Adding a multiplier to the cap could further support maintaining low prices for drugs even as higher-value uses are discovered.

Long-Term Financing

> Should the state, insurer, drug manufacturer, or other entity bear the risk of receiving future payments?

Long-term financing arrangements have the potential to increase Medicaid drug spending by reducing states' ability to negotiate price concessions based on their ability to afford high-cost medications within a single fiscal year. Although states must generally cover all drugs in their Medicaid program, they can use utilization management to restrict access as a tool to negotiate price concessions from manufacturers.

Protected Classes

> Should manufacturers of drugs who have increased their prices over a particular lookback period or have not provided a discount be allowed to be included in the protected classes? Should drugs for which a price increase has not been observed over a particular lookback period be treated differently when determining the exceptions criteria for protected class drugs?

While the Medicare Part D protected classes policy limits the ability of plans to exclude drugs, Pew's analysis suggests little effect on spending currently, though cost-saving potential could increase with the introduction of new drugs into the protected classes.[41] The limited information on rebates in Medicare Part D suggests that drugs within the protected classes have similar rebates to those outside of the protected classes; however, this does not preclude the possibility that plans could obtain higher-than-average rebates for these products if they had a greater ability to exclude them from coverage.[42] Exceptions to the protected classes policy, such as excluding brand drugs when a generic is available or excluding extended-release

[41] "Policy Proposal: Revising Medicare's Protected Classes Policy," Pew Charitable Trusts, March 7, 2018, http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy.

[42] "Among 40 drugs identified by Medicare as having high total spending, high per-user spending, or large price increases in 2014, the average rebate was 17.8 percent. Of these 40 drugs, about a third (13) were in protected classes and accounted for roughly one-third (30 percent) of the spending on those 40 drugs. As the rebates on these 40 drugs were consistent with rebates across all Part D brand-name drugs, this may suggest that rebates on protected-class drugs are consistent with other brand-name drugs. However, it does not preclude the possibility that plans could obtain higher-than-average rebates for these products if they had a greater ability to exclude them from coverage." "Policy Proposal: Revising Medicare's Protected Classes Policy," Pew Charitable Trusts, March 7, 2018, http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy.

or multiple formulations of a covered product, have also resulted in more restrictive formularies in Medicare Part D for the anticonvulsant class in comparison with commercial insurers.[43]

Price Reporting Requirements and Incentive Structures

The RFI solicits comment on the relationship between federal price reporting requirements and various drug pricing contract mechanisms. As we discuss below, some transactions used in existing innovative drug pricing arrangements are already exempted from price reporting requirements. The growth of these arrangements suggests that price reporting requirements are not a categorical barrier to innovative drug pricing contract mechanisms.[44] Any changes to existing requirements should balance (1) the risk of higher prices to Medicaid from changing federal price reporting against (2) the need for robust evidence – currently lacking – that new arrangements between payers and manufacturers reduce spending. Here, we specifically address the concerns raised in the RFI and identify the relevant exemptions; we also address how changing current price reporting requirements may impact federal healthcare programs.

As discussed below, the Medicaid best price requirement does not pose a barrier to price negotiation in commercial insurance markets, as discounts or rebates provided to PBMs are excluded from best price. Because these rebates are excluded from best price, any value-based agreement based on rebates to PBMs would be unlikely to be affected by best price; indeed, the proliferation of value-based agreements suggests that best price is not an insurmountable barrier. Best price may be a barrier to negotiations with correctional facilities, as sales to these entities can trigger best price; sales of emergency treatments to first responders and community groups (e.g., naloxone or epinephrine) may also trigger best price.

To support the ability of correctional facilities, first responders, and community groups to negotiate discounts, consideration should be given to modifying the statute to exclude direct sales to these entities from the best price calculation.

> Does the Best Price reporting requirement of the Medicaid Drug Rebate Program pose a barrier to price negotiation and certain value-based agreements in other markets, or otherwise shift costs to other markets?
>
> How would excluding these approaches from Average Manufacturer Price (AMP) and Best Price (BP) calculations impact the Medicaid Drug Rebate program and supplemental rebate revenue? How would these exclusions affect Average Sales Price (ASP) and 340B Ceiling Prices?

[43] Kelly Brantley, Jacqueline Wingfield, and Bonnie Washington, "An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans," Avalere Health (2013), http://avalere.com/research/docs/Anticonvulsants_in_Part_D_and_Commercial_Health_Insurance.pdf.

[44] Kaltenboeck, A., Bach, P. "Value-based pricing vs. outcomes-based contracting: Frequently asked questions," Drug Pricing Lab, Memorial Sloan Kettering, June 21, 2017, https://drugpricinglab.org/our-work/value-based-pricing-vs-outcomes-based-contracting/. ("Outcomes-based contracts have been announced in the United States for Repatha, Praluent, Entresto, Actonel, and Enbrel, among others. It seems unlikely that these contracts could be in the field and violating current Medicaid Best Price rules.")

Current CMS best price regulations explicitly exclude rebates and discounts to PBMs, stating that "Best price excludes … PBM rebates, discounts, or other financial transactions except their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level."[45] CMS excluded PBM rebates from best price because PBM rebates are excluded from the calculation of AMP by statute;[46] as part of an attempt to harmonize the AMP and best price calculations, CMS specifically enumerated PBM rebates as excluded from best price.[47] This is consistent with the best price statute, which makes clear that only transactions to certain entities – wholesalers, retailers, providers, HMOs, nonprofit entity, or governmental entity – can set best price.[48] Rebates to insurers, aside from HMOs, should also be exempt from best price inclusion, as insurers are not among the list of best price-eligible entities.

Similarly, AMP and ASP should not be affected by value-based arrangements with insurers or PBMs. Rebates or discounts to insurers and PBMs are specifically excluded from AMP. Insurers are also exempt from ASP, because ASP relies on the best price inclusion and exclusion criteria for its calculations, rebates and discounts to PBMs.[49] 340B ceiling prices, which rely on the AMP and best price calculations, are similarly unaffected by value-based arrangements with insurers and PBMs.

However, drugs that are inhaled, infused, instilled, implanted, or injected and that are not generally dispensed through retail community pharmacies (called "5i drugs") may have their AMPs affected by value-based arrangements, because these drugs have a separate AMP calculation methodology that includes rebates and discounts to PBMs and insurers.[50] If value-based discounts are included in these drugs' AMPs, the resulting reduction in AMP may reduce Medicaid rebate payments, as the rebate percentage would be calculated from a lower AMP. However, because AMP is an average calculation, value-based rebates or discounts would need reach substantial volumes to materially affect the overall average AMP. Therefore, there is currently little reason to alter 5i AMP reporting; this could be re-evaluated if value-based agreements become more prevalent. (Note: Unlike AMP, the best price calculation does not differ for 5i drugs, meaning that rebates or discounts to insurers and PBMs remain exempt from the best price calculation for 5i drugs. This also means that the ASPs for these drugs are not affected by value-based arrangements.)

> What benefits would accrue to Medicare and Medicaid beneficiaries by extending the time for manufacturers to report restatements of AMP and/or BP reporting, as outlined in 42 CFR 447.510, to accommodate adjustments because of possible extended VBP evaluation timeframes? Is there a timeframe CMS should consider that will allow manufacturers to restate AMP and BP without negative impact on state rebate revenue?

[45] 42 C.F.R. §447.505(c)(17)
[46] 42 U.S.C. §1396r-8(k)(1)(B)(i)(IV)
[47] 77 Fed. Reg. 5336
[48] 42 U.S.C. §1396r-8(c)(1)(C)
[49] Notably, this means that Medicare Part B payments based on ASP do not reflect average discounts available to PBMs and insurers.
[50] 42 U.S.C. §1396r-8(k)(1)(B)(i)(IV)

In addition, no changes to the definitions of bundled sale, free good, unit, or best price are needed; because these terms all address how drugs are sold, not how they are reimbursed, they should not be implicated in value-based arrangements with payers. Exclusions to AMP and best price for orphan drugs are also unnecessary to facilitate value-based arrangements given the existing exemptions from these calculations. Because value-based arrangements should not affect government price reporting, any changes to price reporting requirements in the name of value-based arrangements may have unintended consequences that could increase Medicaid drug spending. [51]

If commercial rebates and discounts to PBMs or insurers were included in AMP, as already happens for 5i drugs, this would increase Medicaid spending, because the 23.1% Medicaid rebate would be calculated based on a lower AMP. Similarly, if manufacturer drug discount card programs were included in AMP, Medicaid spending would likely increase because of decreased rebate payments from manufacturers.

Conversely, removing the cap on inflation rebates in the Medicaid program would likely reduce federal drug spending and has the additional potential to reduce drug prices for payers and patients in the commercial insurance market. Removing the cap would return the program to the pre-2010 state in which a manufacturer taking a large price increase could owe a rebate greater than the cost of the drug – meaning that manufacturers were losing money on these drugs when used by Medicaid beneficiaries. [52,53] This policy may discourage manufacturers from taking large price increases. For example, consider the price increase for the drug Daraprim: in Congressional testimony, Nancy Retzlaff, the Chief Commercial Officer for Turing Pharmaceuticals, testified that two-thirds of Daraprim sales were through

What modifications could be made to the following regulatory definitions in the current Medicaid Drug Rebate Program that could facilitate the development of VBP arrangements: 1) bundled sale; 2) free good; 3) unit; or 4) best price?

Would providing specific AMP/BP exclusions for VBP pricing used for orphan drugs help manufacturers that cannot adopt a bundled sale approach?

The Department is also interested in learning more about the effect of excluding payments received from, and rebates or discounts provided to pharmacy benefit managers (PBMs) from the determination of Average Manufacturer Price. What impacts would these changes have on list prices, price increases over time, and public and private payers? What data would support or refute the premise described above?

CMS regulations presently exclude manufacturer sponsored drug discount card programs from the determination of average manufacturer price and the determination of best price. What effect would eliminating this exclusion have on drug prices?

[51] The HHS OIG has repeatedly cited concerns about bundled sales increasing costs to federal payers; in 2016, the OIG reached a $785 million settlement with a pharmaceutical manufacturer for underpayment of Medicaid rebates due to allegedly falsified AMP reporting from bundled sales. HHS OIG. "Taxpayers Could See Billions Saved As the Result of HHS OIG Work, New Report Says," Dec. 13, 2016, https://oig.hhs.gov/newsroom/news-releases/2016/oig-work.asp.

[52] 42 U.S.C. §1396r-8(c)(2)(D)

[53] Some manufacturers took the position that the rebate could not exceed AMP and did not make these payments, while other manufacturers honored the negative rebates. *See*, Ruskin, A. "Price Reporting and Governmental

government programs and were priced at $0.01 per pill (the lowest price with the cap in place); this figure appears to aggregate both sales under the Medicaid and 340B programs.[54] A conservative estimate of the inflation rebate for Daraprim, based on the change in price from 2014 to 2015, suggests that without the inflation penalty cap, the rebate on Daraprim would have been approximately $900, $150 more than the $750 per pill price;[55] in 2015, Medicaid paid for nearly 120,000 Daraprim pills.[56] While Turing may have found it a profitable strategy to only earn revenue on one-third of drug sales, had Turing lost $150 per pill for every Medicaid sale, it may not have taken as large a price increase. Eliminating the Medicaid rebate cap may discourage this type of price increase behavior, benefiting not only Medicaid but also private insurers.

> When is this limitation [Medicaid rebate cap] a valid constraint upon the rebates manufacturers should pay? What impacts would removing the cap on the inflationary rebate have on list prices, price increases over time, and public and private payers?

Pew conducted an analysis of the number of drugs affected by the Medicaid rebate cap in 2017 and the potential increased rebate payments to Medicaid.[57] This analysis found that approximately 270 brand drugs would have triggered the rebate cap in 2017. Additional rebates on these drugs would have exceeded $100 million; diabetes treatments and older drugs that experienced large price spikes comprised the majority of these additional rebates.

In order to discourage price increases, a manufacturer would need to find it more profitable to take a smaller price increase and avoid the additional rebate to Medicaid rather than take a larger increase and pay the additional rebate. These revenue reductions may not be sufficient to cause manufacturers to reduce prices or avoid taking price increases; however, this could change with the addition of a multiplier to the Medicaid inflation rebate.[58]

Rebate Issues Arising from the Healthcare Reform Law – An Early Assessment," Morgan Lewis, July 6, 2010, https://www.morganlewis.com/pubs/price-reporting-and-governmental-rebate-issues-arising-from-the-healthcare-reform-lawan-early-assessment.

[54] House Oversight and Government Reform Committee, "Developments in the Prescription Drug Market: Oversight," Feb. 4, 2016, https://oversight.house.gov/hearing/developments-in-the-prescription-drug-market-oversight/.

[55] The price of Daraprim in 2014 was $13.50 per pill and increased to $750 in 2015; the change in Consumer Price Index – Urban from 2014 to 2015 was 0.1%. Domonoske, C. "No Comment from Grinning Martin Shkreli at House Hearing on Drug Prices," National Public Radio, Feb. 4, 2016, https://www.npr.org/sections/thetwo-way/2016/02/04/465548279/no-comment-from-grinning-martin-shkreli-at-house-hearing-on-drug-prices; "Historical Consumer Price Index for All Urban Consumers," Bureau of Labor Statistics, https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-201805.pdf.

[56] CMS, "Medicaid Drug Spending Dashboard," https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Medicaid.html.

[57] This analysis was performed using historical Medicaid utilization data; because the AMP for brand drugs is based on sale prices to pharmacies and because Medicaid is required to reimburse pharmacies based on their acquisition cost for drugs, Medicaid reimbursement to pharmacies should approximate the AMP for brand drugs. Manual review removed 5i drugs that were not predominantly self-administered and thus likely to use 5i AMP.

[58] Horn, T, Dickson, S. "Modernizing and Strengthening Existing Laws to Control Drug Costs," Health Affairs Blog, March 31, 2017, https://www.healthaffairs.org/do/10.1377/hblog20170331.059428/full/.

Cost Shifting and Cross-Subsidization

The RFI raises the important concern that required discounts, taxes, or fees for some purchasers can lead to price increases for all purchasers. However, the available evidence does not support the proposition for brand drugs; there may be an effect in the generic market.

Under economic theory, cost-shifting should only occur when a market is fully competitive and goods are being sold at marginal cost. In these markets, any required discounts, taxes, or fees would increase the costs of production and would be expected to result in higher prices. Prices would still equal marginal cost. Empirical studies demonstrate that generic drug markets can operate as competitive markets with prices approaching marginal cost.[59,60]

In contrast, competition in the brand drug market is influenced by Food and Drug Administration (FDA) exclusivity and the patent system, which are intended to spur drug development by protecting brand drugs from competition during their exclusivity periods.[61] In these markets, manufacturers set prices at willingness to pay, not marginal cost.[62]

In a monopoly market, required discounts, taxes, or fees in one sector of the market do not affect prices in other market sectors, because those prices should already reflect buyers' maximum willingness to pay.[63] For example, if a manufacturer sells a drug to two different purchasers, an additional, mandatory, discount for purchaser A should not affect the price the manufacturer charges purchaser B.

Cost-shifting has been extensively studied in the context of Medicare hospital payments, where studies show that Medicare payment reductions have not resulted in higher

Does the Best Price reporting requirement of the Medicaid Drug Rebate Program pose a barrier to price negotiation and certain value-based agreements in other markets, or otherwise shift costs to other markets?

How have these changes [Affordable Care Act taxes and rebates] impacted manufacturer list pricing practices? Are government programs being cross-subsidized by higher list prices and excess costs paid by individuals and employers in the commercial market? If cross-subsidization exists, are the taxes and artificially depressed prices causing higher overall drug costs or other negative effects?

How has the growth of the 340B drug discount program affected list prices? Has it caused cross-subsidization by increasing list prices applicable in the commercial sector?

[59] Suh, DC, et al. "Effect of multiple-source entry on price competition after patent expiration in the pharmaceutical industry." Health services research 35.2 (2000): 529.
[60] Reiffen, David, and Michael R. Ward. "Generic drug industry dynamics." Review of Economics and statistics 87.1 (2005): 37-49.
[61] Suh, DC, et al. "Effect of multiple-source entry on price competition after patent expiration in the pharmaceutical industry." Health services research 35.2 (2000): 529.
[62] Suh, DC, et al. "Effect of multiple-source entry on price competition after patent expiration in the pharmaceutical industry." Health services research 35.2 (2000): 529.
[63] Lu, Z. John, and William S. Comanor. "Strategic pricing of new pharmaceuticals." Review of economics and statistics 80.1 (1998): 108-118.

costs for other payers and may actually have reduced costs to private payers.[64,65,66] The limited evidence in the pharmaceutical sector found that the introduction of Medicaid rebates did not increase prices of brand drugs without competition.[67] It therefore appears unlikely that discounts, fees, or taxes under federal programs have resulted in higher prices for brand drugs.

While there may be some impact in the generic market, generic prices for the majority of drugs have continued to decline over time even with these increased costs,[68] suggesting that the competitive nature of the market causes generic manufacturers to continuously seek to lower costs. Moreover, generics comprise a relatively small proportion of national drug spending (23 percent) relative to their prescription volume (90 percent),[69] and any marginal reduction in generic prices from eliminating cost-shifting would be unlikely to materially affect drug spending.

Generic Drug Pricing and Development

Impact of Government Programs on Generic Pricing

The generic reimbursement methodologies used by the federal Medicare and Medicaid programs are unlikely to cause underpricing of generic drugs, and there is no evidence of underpricing caused by these programs independent of the overall market for generic drugs. Federal programs use reimbursement strategies similar to private payers to obtain the best prices on generic drugs, encouraging manufacturers to compete on price for their sales to pharmacies. Because these programs use similar tools to private payers, they are unlikely to uniquely contribute to any reduction in generic competition from underpricing.

> Are government programs causing underpricing of generic drugs, and thereby reducing long-term generic competition?

Indeed, rather than causing underpricing, the Medicaid program may currently reimburse pharmacies above cost for generic drugs. State Medicaid programs are required to reimburse pharmacies based on a measure of acquisition cost for drugs.[70] This requirement was intended to reduce Medicaid overpayments to pharmacies from relying on inflated list prices that did not reflect actual pharmacy costs.[71] To inform pharmacy reimbursement

[64] Robert Wood Johnson Foundation. "A Review of the Evidence on Hospital Cost-Shifting," May 2011, http://hcfo.org/files/hcfo/HCFO%20Brief%20May%202011%20FINAL.pdf.
[65] White, C. "Contrary to cost-shift theory, lower Medicare hospital payment rates for inpatient care lead to lower private payment rates." Health Affairs 32.5 (2013): 935-943.
[66] Frakt, AB. "How much do hospitals cost shift? A review of the evidence." The Milbank Quarterly 89.1 (2011): 90-130.
[67] Morton, FS. "The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules," Rand Journal of Economics 28, no. 2 (1997): 269.
[68] HHS Assistant Secretary for Planning and Evaluation. "Understanding Recent Trends in Generic Drug Prices," Jan. 27, 2016, https://aspe.hhs.gov/system/files/pdf/175071/GenericsDrugpaperr.pdf.
[69] IQVIA. "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," April 2018.
[70] 42 C.F.R. § 447.512
[71] 77 Fed. Reg. 5318, 5345 ("Several reports issued by the OIG have shown that AWP is often a significantly inflated price, and not necessarily reflective of a pharmacy's actual purchase price for a drug.")

schedules, the federal Medicaid program conducts a survey of pharmacy acquisition costs, called the National Average Drug Acquisition Cost (NADAC) survey.[72] States also have flexibility to use other metrics if they do not exceed federal maximums.[73] This survey averages the prices pharmacies pay to wholesalers for drugs, but it excludes any rebates or other discounts that manufacturers provide directly to pharmacies (a common practice for generic drugs, but not brand drugs).[74,75] These rebates and discounts, however, are included in the generic manufacturer's calculation of AMP, which is used to establish mandatory rebates from the manufacturer to state Medicaid programs on generic drugs – meaning that the rebate Medicaid receives is typically calculated from a lower price than what it pays the pharmacy. According to the May 2018 Medicaid Federal Upper Limit pricing data, 42% of drugs have a NADAC that is more than 175% of AMP,[76] implying that these additional discounts and rebates can be significant. The Medicaid rebate is designed to give Medicaid programs a 13 percent rebate on the price of generic drugs, but the discrepancy between AMP and NADAC undermines that design. Consider a drug with a $20 NADAC and a $10 AMP – the Medicaid program would pay the pharmacy $20 even though the pharmacy's net cost was only $10, and the manufacturer would only pay Medicaid a $1.30 rebate (13% of $10 (AMP), rather than $20 (NADAC)). Because of this dynamic, Medicaid may actually be subsidizing both pharmacies and generic manufacturers, overpaying pharmacies and requiring rebates from generic manufacturers that are not based on the amounts Medicaid actually reimburses pharmacies for these drugs.

For physician-administered drugs, both Medicaid[77] and Medicare Part B[78] group all generic versions of a drug into the same reimbursement code. Under this approach, reimbursement is based on the average cost of drugs in the group. This gives providers a financial incentive to use the lowest cost generic product within a reimbursement code and encourages generic manufacturers to compete to be the lowest price option. These mechanisms support a market-based approach to generic pricing; if the number of competitors in one reimbursement code declines and the remaining manufacturers raise prices, additional competitors are encouraged to enter with lower prices. While government programs may encourage manufacturers to lower the prices of generic products, they are doing so for competitive reasons – government programs are not forcing an underpricing of generic products.

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[72] CMS. "Retail Price Survey," https://www.medicaid.gov/medicaid/prescription-drugs/retail-price-survey/index.html.
[73] CMS. "Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State, Quarter Ending March 2018," https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/drug-reimbursement-information/index.html.
[74] CMS. "Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs," Nov. 2013, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf.
[75] Libermand, SM, Ginsburg, PB. "Would price transparency for generic drugs lower costs for payers and patients?," Brookings, June 14, 2017, https://www.brookings.edu/research/would-price-transparency-for-generic-drugs-lower-costs-for-payers-and-patients/.
[76] CMS. "Pharmacy Pricing," https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html.
[77] 42 C.F.R. § 447.514
[78] HHS OIG, "Medicare Payments for Newly Available Generic Drugs," OEI-03-09-00510, Jan. 2011, https://oig.hhs.gov/oei/reports/oei-03-09-00510.pdf.

Access to Samples for Development of Generic and Biosimilar Products

While the Risk Evaluation and Mitigation Strategy (REMS) statute states that manufacturers shall not use REMS to block or delay approval of a generic application, there is no affirmative requirement to provide samples and the statute does not provide authority for FDA to compel a manufacturer to provide samples.[79] Some brand manufacturers have argued that their REMS programs prevent them from providing these samples.[80] In addition, some non-REMS drugs are also subject to limited distribution that impairs a potential competitor from obtaining reference product necessary to develop a generic drug. This was a key element of Turing Pharmaceuticals' strategy for increasing the price of Daraprim,[81] and the Federal Trade Commission has opined that these arrangements may violate antitrust law.[82] Moreover, these limited distribution systems can affect patient access to medication.[83] Therefore, any policy solution to address limited distribution systems should not limit legal remedies to only REMS-affiliated limited distribution systems.

Should additional steps be taken to review existing REMS to determine whether distribution restrictions are appropriate? Are there terms that could be included in REMS, or provided in addition to REMS, that could expand access to products necessary for generic development? Are there other steps that could be taken to facilitate access to products that are under distribution limitations imposed by the manufacturer?

Like some generic drug developers, companies engaged in biosimilar and interchangeable product development may encounter difficulties obtaining sufficient samples of the reference product for testing. What actions should be considered to facilitate access to reference product samples by these companies?

Instead, Congress could leverage existing enforcement authorities under the Medicare and Medicaid programs to penalize companies that withhold access to samples from generic manufacturers when generic or biosimilar manufacturers satisfy appropriate safety criteria. Congress could make provision of samples to qualified generic or biosimilar manufacturers a condition for drug coverage under federal programs and require CMS and FDA to establish procedures for generic and biosimilar manufacturers to request samples,

[79]Food Drug and Cosmetic Act § 355-1(f)(8). ("No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 355(b)(2) or (j) of this title or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.")

[80] "Statement from FDA Commissioner Scott Gottlieb, M.D., on new policies to reduce the ability of brand drug makers to use REMS programs as a way to block timely generic drug entry, helping promote competition and access," May 31, 2018, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm609365.htm.

[81] Committee on Oversight and Government Reform, Democratic Staff. "Memorandum re: Documents Obtained by Committee from Turing Pharmaceuticals," Feb. 2, 2016, https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Turing%20Documents.pdf.

[82] FTC. "FTC Amicus Brief: Improper Use of Restricted Drug Distribution Programs May Impede Generic Competition," June 19, 2014, https://www.ftc.gov/news-events/press-releases/2014/06/ftc-amicus-brief-improper-use-restricted-drug-distribution.

[83] NASTAD. "Letter to HRSA OPA on Daraprim Access," Sept. 22, 2015, http://files.nastad.org/media/NASTAD-Letter-to-OPA-on-Daraprim.pdf.

including standards for compliance with REMS programs. If a generic or biosimilar manufacturer demonstrates through a complaint that a brand manufacturer is not meeting its obligation to provide samples (after following the specified procedures), the OIG could use existing authorities[84] under the Social Security Act to levy Civil Monetary Penalties (CMPs) against the manufacturer that is withholding samples. CMS could be given additional authority to reduce reimbursement for the affected products or all products by the brand manufacturer, require additional Medicaid rebates, or work with OIG to use its exclusion authority to remove coverage for the drug. This policy would create a financial disincentive for brand manufacturers to inhibit generic or biosimilar development.

Pharmacy Benefit Managers and Rebates

The RFI solicits comments on a variety of issues relating to PBMs and the use of rebates to reduce drug spending. Below, we respond directly to these questions; we also offer some general comments on PBMs and their role within the drug spending landscape.

> Do PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher rebates) rather than lower prices?
>
> Do higher rebates encourage benefits consultants who represent payers to focus on high rebates instead of low net cost?

The tasks PBMs perform in the drug spending landscape – designing formularies, administering benefits, and negotiating discounts – are a necessary part of drug benefit administration. Without PBMs, these functions would be performed by insurance companies or other entities. In fact, insurers perform these functions for other healthcare services (e.g., hospital and physician benefits). The widespread use of PBMs suggests that insurers find it more efficient or profitable to outsource these functions rather than performing them in-house. By combining the purchasing power of multiple insurers and self-insured companies, PBMs appear to have been able to achieve greater efficiencies and discounts than these players could on their own – even after the PBMs' profits are considered. If PBMs were not generating cost-savings for insurers, presumably insurers would perform these functions themselves. Indeed, according to CMS, "post point-of-sale concessions [PBM rebates] lessen plan liability and put downward pressure on beneficiary premiums."[85] The drop in Medicare Part D premiums for 2018 suggests that PBMs have been effective in controlling drug spending, at least for the portion of benefit for which plans are liable.[86]

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[84] HHS OIG. "Civil Monetary Penalty Authorities," https://oig.hhs.gov/fraud/enforcement/cmp/cmpa.asp. If a requirement to provide samples is added as a new obligation under the Medicare and Medicaid programs, the existing authorities should apply to the new obligation.

[85] CMS. "Medicare Part D – Direct and Indirect Remuneration (DIR)," Jan. 19, 2017, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.

[86] In 2017, the base beneficiary premium was $35.63; in 2018, $35.02. CMS, "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information," July 29, 2016, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2017.pdf, and CMS, "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information," July 31, 2017, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2018.pdf.

The combined negotiating power that has made PBMs successful in controlling costs, however, may discourage further competition if PBMs' negotiating power eclipses the power of manufacturers or insurers. For example, a large PBM could tell a manufacturer that it would not prefer or exclude its drugs from formulary if that manufacturer negotiated with a new, smaller PBM or directly negotiated with an insurer. These type of exclusion contracts have long been a concern for hospitals negotiating with insurers over network inclusion.[87] Similarly, in a consolidated PBM market, large PBMs may not compete on rates for smaller insurers or self-insured companies, finding their business to be too small; if smaller PBMs targeting these firms are unable to enter the market, these firms may pay more than they would in a competitive PBM market.[88] Federal antitrust scrutiny may be appropriate for PBMs, using similar approaches as the hospital market.[89]

Policies that attempt to reduce PBMs' current role market would effectively shift negotiation of discounts from PBMs to insurers or other intermediaries. Policies should be assessed on whether this shift in power would result in greater overall prices concessions. Reducing PBMs' ability to extract price concessions from drug manufacturers may raise overall drug spending.

For example, the RFI is concerned whether the practice of PBM rebate negotiations encourages higher drug list prices so that PBMs can obtain more revenue as a percent of rebates. While current PBM contracting arrangements may create these incentives, there is no evidence that net prices for drugs would be lower without PBM rebates. As discussed previously, competition on publicly available prices may result in price-fixing by manufacturers, meaning that list price competition may increase drug spending. Moreover, insurers and self-insured companies have an incentive to achieve the lowest net cost possible, and their continued use of PBMs suggests that the net costs received by the insurer, even accounting for PBM profits, still achieve greater cost-savings that the insurer could achieve independently.

> Do payers manage formularies favoring benefit designs that yield higher rebates rather than lower net drug costs? How are beneficiaries negatively impacted by incentives across the benefits landscape (manufacturer, wholesaler, retailer, PBM, consultants and insurers) that favor higher list prices?
>
> How can these incentives be reset to prioritize lower out of pocket costs for consumers, better adherence and improved outcomes for patients?

[87] *See, e.g.,* Lomax, D and Mattioli, M. "Provider Value-Based Contracting: Antitrust and Competitive Risks," American Bar Association, https://www.americanbar.org/content/dam/aba/administrative/healthlaw/05_networking_contracting_in_the_brave.authcheckdam.pdf. (discussing United States v. United Regional Healthcare System, Complaint ¶ 49, Civil Action No. 7:11-cv-00030 (N.D. Texas, Feb. 25, 2011), "The United States Department of Justice, Antitrust Division, entered into a consent decree with the hospital prohibiting it from entering into any contracts with payers that discounted rates conditioned on the insurer's not entering into an agreement for the purchase of services from another provider.")

[88] John B. Kirkwood, Powerful Buyers and Merger Enforcement, 92 B. U. L. REV. 1483 (2012).

[89] FTC. "Industry Guidance: Competition in the Health Care Marketplace," https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care.

The savings achieved by PBMs, however, do not address whether incentives in the PBM market increase list prices. Even without PBM incentives for higher list prices, profit-maximizing manufacturers would increase prices as consumer or insurer willingness to pay increases. Assuming, though, that PBM rebate incentives cause list prices to increase, this increasing gross-to-net difference is only a problem if patients are facing list prices. For insured patients, the use of list prices as a reference for cost-sharing, such as coinsurance, is the choice of the insurer. The most direct approach to shield patients from high cost-sharing is through insurance regulation. As discussed in more detail in this letter's Patient Cost-Sharing section (below), using price to manage drug utilization discourages both clinically appropriate and inappropriate utilization, which may lead patients to forgo necessary medicines. Instead of tying cost-sharing to the price, list or net, of a drug, insurers could be required to use clinical criteria to determine access to medications and cost sharing. This approach may help to reduce income-related disparities in health care access and outcomes.

The Medicare Part D program may be a model for managing the relationship between PBMs and insurers or self-insured companies. The Part D program requires plans to report all Direct and Indirect Remuneration (DIR) received by either the plan or a PBM, regardless of whether the DIR is retained by the PBM or passed on to the plan.[90] This confidential transparency allows Medicare to require the plan to accurately create premium rates that reflect the net costs of drugs to the plan and PBM. Insurers and PBMs are already familiar with these requirements, and extending them to other health insurance products, such as through the Secretary's ability to regulate Qualified Health Plans, may help ease any information asymmetry between PBMs and insurers that could increase costs.

The careful regulation of DIR in Part D has created incentives for insurers to compete on achieving the lowest possible drug costs to attract more beneficiaries to their plan offerings. Under the Part D program, insurers receive a fixed per-member profit based on the profits achieved in their non-Medicare plan offerings.[91] If the insurer achieves greater savings than anticipated in the plan bid, those savings are shared with Medicare and will reduce the plan's bid in the next year. This model, combined with the PBM rebate transparency achieved through DIR reporting, encourages insurers and PBMs to compete on lowest cost rather than rebate spread, as lower costs translate into lower premiums, encouraging more beneficiaries to select the insurer's plan. Because the plan's profits are primarily generated through the volume of pre-defined, per-member profits, plans and PBMs can only increase their revenue from enrolling more beneficiaries, not through retaining a

What should CMS consider doing to restrict or reduce the use of rebates? Should Medicare Part D prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers, and require these contracts to be based only on a fixed price for a drug over the contract term?

What should CMS consider doing, under current authorities, to create incentives for Part D drug manufacturers committing to a price over a particular lookback period? How long should the lookback period be?

[90] 42 C.F.R. § 423.308

[91] "This bid is based on the sponsor's estimate of its anticipated drug costs, as well as its administrative costs, which include nonpharmacy expenses and expected profit. Expected profit, also known as the gain/loss margin, is

higher portion of the rebate spread.[92] This model has been effective, leading to lower-than-projected Medicare Part D costs and a decrease in member premiums in 2018.[93] Given the success of this model, the use of rebates in the Medicare Part D program should not be restricted without strong quantitative models that project additional savings.

340B Drug Pricing Program

The RFI solicits comments on various aspects of the 340B program, including the relationship of 340B discounts to drug prices and spending by various payers as well as technical aspects of the program's administration. We respond to these questions in the context of how the 340B program interacts with the broader healthcare system.

The 340B program requires drug manufacturers to provide discounts to certain hospitals and other health care entities as a condition of participating in the federal Medicare Part B and Medicaid programs.[94] In 2015, these discounts reduced drug manufacturer revenues by an estimated 1.9%.[95] 340B discounts rely on the Medicaid drug rebate program's unit rebate amount formula, essentially providing the Medicaid rebate to 340B covered entities as an up-front discount. This discount has two components: a base discount percentage (23.1% for brand drugs) and an inflation rebate, which requires

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the additional revenue the sponsor requires above the amount needed to cover drugs costs and other expenses." HHS OIG, "Medicare Part D Reconciliation Payments for 2006-2007," OEI-02-08-00460, Sept. 2009, https://oig.hhs.gov/oei/reports/oei-02-08-00460.pdf.

[92] "CMS requires sponsors to estimate their expected profits based on accepted actuarial techniques." HHS OIG, "Medicare Part D Reconciliation Payments for 2006-2007," OEI-02-08-00460, Sept. 2009, https://oig.hhs.gov/oei/reports/oei-02-08-00460.pdf. If the plan over- or under-estimates spending, it will share losses or profits with Medicare under "risk-corridors." While this may encourage a plan to over-estimate spending to keep profits, actuarial rules hinder plans ability to inflate costs and any over-estimation in one year would reduce estimates for the following year. Further, overestimation would increase premiums, which may discourage enrollment. *See* "Medicare Part D bids are due the June prior to the benefit year, based upon experience for the year two-years prior to the benefit year." American Academy of Actuaries, "Medicare Part D Accounting Practice Note," April 2008, https://www.actuary.org/files/publications/Practice_Note_Medicare_Part_D_accounting_practice_note_april2008.pdf

[93] "Compared to the 2016 report, actual premiums, government contributions, and benefit payments for 2017 were all significantly lower than projected primarily for three reasons: (i) the drug rebates were higher than previously assumed; (ii) the actual drug trend was lower due to a decline in hepatitis C drug spending; and (iii) the 2016 reinsurance reconciliation amounts paid in 2017 were lower than projected in the 2016 report." 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, pp. 101-102, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf. In 2017, the base beneficiary premium was $35.63; in 2018, $35.02. CMS, "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information," July 29, 2016, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2017.pdf, and CMS, "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information," July 31, 2017, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2018.pdf.

[94] 42 U.S.C. § 1396r–8(b)(3)(A)(iii) (Medicare Part B) and 42 U.S.C. § 1396r–8(a)(5)(A) (Medicaid).

[95] Coukell AJ, Dickson S. "Reforming the 340B Drug Pricing Program: Tradeoffs Between Hospital and Manufacturer Revenues." JAMA Intern Med. May 21, 2018.

an additional dollar-for-dollar discount for any price increases greater than the rate of inflation. Persistent drug price increases greater than inflation have led to 340B discounts of over 50% for many brand name drugs – frequently, the inflation discount may exceed the base discount.[96]

This inflation discount is important, as it may actually discourage manufacturers from taking larger price increases. If a substantial portion of a manufacturer's sales are to 340B entities and Medicaid beneficiaries, the manufacturer may find it more profitable to take a smaller price increase and reduce the amount of the inflation penalty. This incentive is compounded by voluntary price protection rebates that manufacturers offer to PBMs – PBMs receive their own inflation rebate from the manufacturer when they reimburse a 340B covered entity at the undiscounted price of the drug, compounding the penalty to the manufacturer for taking price increases greater than inflation.[97] This means the 340B program may play a role in constraining drug price increases.

> What impact has this [growth of the 340B program] had on insurers and payers, including Part D plans?
>
> What are the unintended consequences of this program? Would explicit general regulatory authority over all elements of the 340B Program materially affect the elements of the program affecting drug pricing?
>
> What is the impact on drug pricing given that private insurers oftentimes pay commercial rates for drugs purchased at 340B discounts?

For example, consider a manufacturer of a $1000 brand drug considering a price increase to $1100; the inflation-adjusted price is $1030 (3% inflation), and assume all sales are subject to a PBM rebate which limits price increases to 5% per year. If 10% of the drug's sales are subject to 340B discounts, the manufacturer would find it more profitable to take the $100 price increase; however, if 30% of drug sales were subject to the 340B discount, the manufacturer would prefer to limit the price increase to $30.

New Price	Inflation-Adjusted Price	PBM Price		340B Price				Average Net Price*	
		PBM Inflation Rebate	Net PBM Sale	340B Base Discount **	340B Inflation Penalty	PBM Inflation Rebate	Net 340B Sale^	Low 340B (10%)**	High 340B (30%)**
$1,030	$1,030	$0	$1,030	$238	$0	$0	$792	$1,006	$959
$1,100	$1,030	$50	$1,050	$254	$70	$50	$726	$1,018	$953

*Excludes Medicaid sales, which are unlikely to be subject to PBM rebates.
**Rounded to nearest dollar
^Net sale price realized by the manufacturer, not the 340B covered entity. The PBM inflation rebate does not accrue to the 340B covered entity, but is still realized by the manufacturer on sales to 340B entities.

[96] HHS OIG. "Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D." April 2015, OEI-03-13-00650, available at https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf.
[97] Steven Kaczmarek, Pharmacy manufacturer rebate negotiation strategies: A common ground for a common purpose, Milliman, Nov. 17, 2015, available at http://www.milliman.com/insight/2015/Pharmacy-manufacturer-rebate-negotiation-strategies-A-common-ground-for-a-common-purpose/.

Given this possible effect, reducing the size of the 340B program could actually encourage manufacturers to take greater price increases. If the 340B program has had this constraining effect on drug prices, the 340B program has likely reduced payers invoice spending on drugs (though if payers receive inflation rebates from manufacturers, the net effect on spending may be lower). Any reduction in price increases from the 340B program may be more prominent in the Medicare Part B program, where there are no inflation adjustments or rebates to offset price increases.

More generally, the 340B program affects how revenue from payers is distributed between hospitals and pharmaceutical manufacturers; aside from a possible effect on manufacturer price increases, changes to the program would have a limited effect on drug spending. Because brand manufacturers price drugs at willingness to pay, not marginal cost, the practice of private payer reimbursement of 340B providers at commercial rates would be unlikely to impact drug prices as set by the manufacturer.

Patient Cost-Sharing

The RFI solicits comments on many aspects of patient cost-sharing, affecting both patients with commercial insurance and Medicare coverage. We provide general comments on these aspects of cost-sharing as well as responses to specific inquiries.

Any relationship of patient cost-sharing to the list price of a drug is an issue of insurance benefit design rather than drug pricing. Insurers that use high cost-sharing, whether through high deductibles, co-payments, or co-insurance, are typically choosing to use cost to deter drug utilization or to shift costs from premiums to beneficiary out-of-pocket spending. While tiering out-of-pocket expenses can reduce unnecessary use of expensive drugs, it may also deter appropriate use.[98] Moreover, cost-sharing makes access to care a function of a patient's ability to pay rather than clinical need.

> Too often, these negotiations [PBM rebate] do not result in the lowest out-of-pocket costs for consumers, and may actually be causing higher list prices.
>
> Does the use of manufacturer copay cards help lower consumer cost or actually drive increases in manufacturer list price?

To reduce high cost-sharing and de-link out of pocket costs from drug list prices, the Secretary could use his regulatory authority to establish appropriate cost-sharing limits for Medicare Part D and Qualified Health Plans. These limits could be set so that patients do not forego medically necessary drugs, a practice which may increase overall healthcare costs through higher medical utilization.[99,100]

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[98] "For hospitalizations and prescription drug use, cost sharing likewise reduced more-effective and less-effective care in roughly equal amounts for all participants." Brook, RH., Keeler EB, Lohr KN, et. al., "The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate," RAND Corporation, 2006. https://www.rand.org/pubs/research_briefs/RB9174.html.

[99] Eaddy, Michael T., et al. "How patient cost-sharing trends affect adherence and outcomes: a literature review." Pharmacy and Therapeutics 37.1 (2012): 45.

[100] Zdechlik, M. "Her son couldn't afford insulin and died. Now she's fighting Big Pharma," Minnesota Public Radio, May 11, 2018, https://www.mprnews.org/story/2018/05/11/soaring-insulin-prices-prompt-protest-at-capitol.

Simultaneously, regulatory guidance should allow insurers to engage in more rigorous clinical review of utilization to avoid increasing clinically unnecessary use of high-cost drugs. Limiting utilization based on clinical need rather than patient ability to pay may help reduce the simultaneous escalation of both list prices and manufacturer copay assistance programs without impacting beneficiaries who need financial assistance to afford necessary medicines.

To support insurers in using clinical criteria to manage utilization, the Administration could develop standards to recognize treatment guidelines for various health conditions that establish appropriate clinical criteria for utilization management; insurers with benefit designs consistent with these criteria could receive favorable treatment under federal programs and would be presumed to not be unduly restricting patient access under current beneficiary protections. Federal treatment guidelines already exist for a variety of health conditions, establishing a precedent for this approach.[101,102] Independent consortia, following the model of the Medicaid Drug Effectiveness Review Project (DERP),[103] could be financed by insurers to develop clinical guidelines that meet federal appropriateness criteria. The Administration could expand upon existing formulary guidance[104] to allow insurers to develop processes that would allow for more rigorous utilization management while still allowing beneficiaries access to necessary treatment.

Pharmacy gag clauses are reportedly used to prohibit pharmacists from telling patients if paying cash for a drug would be cheaper than the patient's cost-sharing using their insurance. There is little public data on the existence or prevalence of such clauses, which would be established as part of benefit design. For generic drugs, the higher cost-sharing payment may be a result of administrative simplicity – the insurer has established a fixed co-payment for all generic drugs (e.g., $10), but some drugs may be cheaper when purchased with cash. However, when patients pay with cash, these payments generally do not accrue to their deductible and maximum out-of-pocked limits, which may raise costs to patients overall. In conjunction with establishing appropriate cost-sharing limits and clinical criteria, the Administration should consider issuing regulatory guidance that patient cost-sharing for Medicare

> What purpose do these clauses serve other than to require beneficiaries pay higher out-of-pocket costs? What other communication barriers are in place between pharmacists and patients that could be impeding lower drug prices, out-of-pocket costs, and spending? Should pharmacists be required to ask patients in Federal programs if they'd like information about lower-cost alternatives? What other strategies might be most effective in providing price information to consumers at the point of sale?

[101] HHS. "AIDSinfo: Clinical Guidelines," https://aidsinfo.nih.gov/guidelines.
[102] Department of Veterans Affairs. "VA/DoD Clinical Practice Guidelines," https://www.healthquality.va.gov/HEALTHQUALITY/guidelines/index.asp.
[103] Oregon Health and Science University. "Drug Effectiveness Review Project (DERP)," http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-practice-center/drug-effectiveness-review-project/index.cfm.
[104] CMS. "Medicare Prescription Drug Benefit Manual: Chapter 6 – Part D Drugs and Formulary Requirements," Jan. 15, 2016, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.

Part D and Qualified Health Plans should be the lower of the established cost-sharing payment or the cash price. In cases where the cash price is used, issuers should be required to apply this spending toward the patient's deductible and out-of-pocket limits.

* * *

We appreciate the opportunity to respond to this RFI and commend the Administration for its attention to drug spending. Should you have any further questions, please contact me by phone at 202-540-6392 or via email at acoukell@pewtrusts.org.

Sincerely,

Allan Coukell, BScPharm
Senior Director, Health Programs
The Pew Charitable Trusts