

July 16, 2018

SUBMITTED ELECTRONICALLY VIA WWW.REGULATIONS.GOV

Department of Health and Human Services
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
(May 16, 2018)

Dear Secretary Azar,

We have read with interest and are pleased to submit these comments in response to the above titled RFI. The Drug Pricing Lab at Memorial Sloan Kettering Cancer Center focuses on the development of rational approaches to drug pricing and health insurance coverage that encourage innovation while ensuring patient access and affordability. Our response comprises a summary of our findings on topics that have been raised in the Blueprint, which follow in the order below:

1. Value-based arrangements
2. Competitive acquisition
3. Fixing global freeloading
4. Reducing the impact of rebates
5. Copay discount cards

Value-based arrangements

Arrangements described as “value-based” have become increasingly popular as more drugs enter the market under accelerated approval timelines and with uncertain long term benefits. Typically, these agreements promise to repay to the payer some of a drug’s price if it does not attain a pre-specified outcome over a specific timeframe. Such arrangements are known as outcomes-based contracts (OBCs). However, there is no guarantee that an OBC will result in a value-based price, which is based on an analysis of existing evidence of the drug’s benefits and harms. The analysis on which the price is based should be transparent and replicable, and open to public input. The resulting price should be set at market entry, and adjusted as postapproval evidence becomes available¹. Outcomes-based contracts generally fail to align with these

¹ Kaltenboeck A, Bach PB. Value-Based Pricing for Drugs: Theme and Variations. *JAMA*. 2018;319(21):2165–2166. doi:10.1001/jama.2018.4871

characteristics for several reasons: net prices remain confidential; the underlying analyses cannot be replicated and are not open to public scrutiny or input; and because they are not set at market entry, they offer little benefit to patients. Long-term financing options, such as mortgage models, are subject to the same limitations².

Moreover, OBCs require resources to implement and monitor, may not scale efficiently, and create administrative burdens. There are a number of other approaches at HHS’ disposal that avoid these pitfalls. For example, Medicare could require formulary inclusion for all prescription drugs with value-based prices covered under the Part D program, and lower patient cost sharing for drugs with such prices in Part B. The FDA could also prioritize review of potential competitors for drugs with prices exceeding their value³. Another possibility is indication-based pricing, which allows for reimbursement at different value-based prices for the same drug, depending on which of its multiple indications is being treated⁴.

Regardless of the approach, waivers to Best Price, the anti-kickback statute, and off-label marketing regulations are unlikely to be necessary if a drug’s list price is aligned with evidence of its value in the first place.

Table. Comparison of Value-Based Pricing and Adjacent Concepts

Concept	Definition	Rests on Existing Evidence of Benefit	Aligns Price With Benefit at Market Entry	Examples
Value-based pricing	Price of a drug set on the magnitude of its benefit	Yes	Yes	Pricing of dupilumab according to ICER value-based price
Indication-specific pricing	Drug price specific to each of its uses	Yes	Yes	Tisagenlecleucel sold at 2 different prices for 2 different cancer indications
Outcomes-based contracts	Manufacturer refunds or rebates payer when an agreed-upon outcome is unmet	No	No	Amgen agreement with Harvard Pilgrim to refund cost of evolocumab for treated patients who have a myocardial infarction while taking the drug
Mortgage pricing	Commits a payer to pay for expensive treatments over time	No	No	No known examples
Value-based insurance design	A health benefit design that reduces out-of-pocket expense for high-value medical care and treatments	Yes	No	Prime Therapeutics program to reduce copayment and increase amount dispensed for insulins; Pitney Bowes’ initiative to reduce or eliminate cost sharing for statins and clopidogrel

Abbreviation: ICER, Institute for Clinical and Economic Review.

Source: “Value-Based Pricing for Drugs: Theme and Variations”, *JAMA*²

Competitive Acquisition Program (CAP)

Competitive acquisition allows third party vendors to bid for the right to distribute Part B drugs to providers, while receiving payment directly from Medicare. This arrangement acts in lieu of “buy-and-bill” reimbursement, under which individual providers purchase drugs, and after

² Kaltenboeck A, Bach PB. Value-Based Pricing for Drugs: Theme and Variations. *JAMA*. 2018;319(21):2165–2166. doi:10.1001/jama.2018.4871

³ Bach PB, Pearson SD. Payer and Policy Maker Steps to Support Value-Based Pricing for Drugs. *JAMA*. 2015;314(23):2503–2504. doi:10.1001/jama.2015.16843

⁴ Bach PB. Indication-Specific Pricing for Cancer Drugs. *JAMA*. 2014;312(16):1629–1630. doi:10.1001/jama.2014.13235

administering them to patients, are reimbursed for the cost of the drug plus a markup, encouraging them to select higher priced drugs. During its original implementation, CAP covered all drugs reimbursed in this way, including those with lower unit costs. A revival of CAP would be made more effective by targeting the relatively small number of drugs that account for the majority of provider revenues from markups. This more narrow approach also has the advantage of making CAP easier to use for practices of all sizes, including small providers that struggle with the financial outlay of obtaining the highest priced Part B drugs for their patients⁵. It also creates opportunities for more sophisticated payment models that are difficult to implement under buy-and-bill. For instance, indication-specific pricing requires accounting for each dose and tracking indications. A CAP vendor could offer these capabilities, as well as the neutrality needed to protect against product diversion.

Fixing Global Freeloading

US manufacturers often argue that the US subsidizes the rest of the world's R&D, and suggest that the solution to high US prices is to charge higher prices in other countries. However, findings from our research show that, even after accounting for net price concessions, annual revenue from US price premiums over those in other western countries was \$116 billion for the 15 pharmaceutical manufacturers of the 20 top-selling drugs globally in 2015. These revenues surpassed by a large margin their collective global spending on R&D, which was \$76 billion in the same year.⁶

Reducing the impact of rebates

Drug manufacturers stand by rebates to justify price increases, despite their inflationary effects on patient out-of-pocket spending and overall Medicare spending. Under the current Medicare Part D benefit design, higher list prices, even with more rebate negotiations, offsets spending from plan sponsors and manufacturers to Medicare. Patients do not see the benefit of these confidential price concessions because their payment is based on the higher list price. To ensure that patients benefit directly from the net price concessions arranged by their plans, we have proposed that rebates be "passed through" at the point of sale, basing their out-of-pocket payment on the lower net price.

This policy has two beneficial effects: reducing beneficiaries' out-of-pocket burden, and slowing the rate at which they move through the benefit phases to federal reinsurance, where Medicare bears the majority of costs. Nevertheless, initial actuarial analyses predicted that this would increase premiums. We believe there is some possibility that this result reflect the models

⁵ Bach, Peter. "Competitive Acquisition Program" *Drug Pricing Lab Policy Brief*. Drug Pricing Lab, 14 May 2018. Web. 12 July 2018.

⁶ Yu N, Helms Z, Bach PB. R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices. *Health Aff*. Published March 7, 2017. doi: 10.1377/hblog20170307.059036

simplifying assumptions that did not allow for variation in rebate levels, or account for changes in behavior as the incentives associated with rebating shift away from increasing list prices.

Copay discount cards

Copay assistance diminishes price pressure because patients do not feel the financial burden of their cost-share. It also shifts the financial burden to the payer, who pays the majority of the cost after the patient cost-sharing is met. For government-sponsored programs such as Medicare, this financial risk would be borne by taxpayers, which is the primary reason that this form of copay assistance is not permitted. However, this is not the only form of financial support that allows patients to afford high priced drugs. The table below summarizes, to the best of our knowledge, the different types of support that are currently made available. Although Medicare patients are not eligible for manufacturer-sponsored copay support, they are able to benefit from support through charitable foundations, which can be funded, but not directed towards use of a specific drug, by manufacturers. They are also eligible for means-tested patient assistance programs, and free drugs programs sponsored by manufacturers.

Description	Insurance type			Level of Support	Controlled by	Funding source
	Commercial	Government	Uninsured			
Manufacturer-Sponsored Copay Support Programs that offset patients' copay, coinsurance and deductible expenses	<input type="checkbox"/>	<input checked="" type="checkbox"/> (violates anti-kickback statute)		Drug-specific	MNF	MNF
Charitable Foundation Indication-specific charities to help patients with financial need	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Disease-specific	CF	Charitable donations, incl. from MNF
PBM-Sponsored Copay Support Copay support programs that provide uninsured patients and those on high-deductible plans with discounted drug prices	<input type="checkbox"/>		<input type="checkbox"/>	Drug-specific	PBM	PBM
Patient Assistance Programs Free product for uninsured patients and those on high-deductible health plans	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Drug-specific	CF / MNF	MNF

HCP Samples, Quick Start & Bridge Product Free product provided by manufacturers to health care providers or directly to patients to onboard and maintain them on paid therapy	□	□	□	Drug-specific	MNF	MNF
CF = Charitable foundation; MNF = Manufacturer; PBM = Pharmacy Benefit Manager						

Although some patients may benefit from them, manufacturer-sponsored copay support programs have several undesirable effects. Copay support for such programs is typically recorded as secondary insurance, but can also be managed in other ways, including providing the patient with a debit card, or having the patient mail in a rebate form to receive reimbursement. In general, these approaches allow the copay support to be applied against their deductible and out-of-pocket maximum. In this way, copay assistance undermines benefit designs that make it possible to offer low-cost insurance plans. It also reduces insurers' ability to negotiate for lower prices, creating opportunities for manufacturers to further inflate prices⁷.

There are other policy options that would be more effective at both collecting better information and mitigating the negative effects that we do know exist. These include:

- Requiring pharmaceutical companies to offer similar copay assistance for all patients on their products so companies cannot discriminate against patients who cannot document their financial need, provide assistance to some medications and not others, or limit coupons to only a few prescription fills rather than the duration the patient needs the medication.
- Requiring pharmacies to report copay assistance separately from the patient's cash payment, something copay accumulators are now capturing.
- Including copay assistance as a discount on a drug's price and thus be included in determination of Medicaid's best price floors. Medicaid programs would therefore have access to the same discounts that pharmaceutical companies offer patients with more robust insurance.
- Adopting value-based drug pricing as a long-term solution to high copays and thus copay assistance. The price of a drug would be aligned with its benefits, and insurers would then be expected to include the drug in their formulary with a low copay.

Thank you for the opportunity to provide our comments on this matter. Should you have any questions, please feel free to contact me or the Drug Pricing Lab program director, Anna Kaltenboeck.

⁷ Ubel PA, Bach PB. Copay Assistance for Expensive Drugs: A Helping Hand That Raises Costs. *Ann Intern Med.* 2016;165:878-879. doi: 10.7326/M16-1334

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Bach', written over a light blue rectangular background.

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