



July 16, 2018

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Room 600E
Washington, DC 20201

Submitted electronically to: www.regulations.gov

Re: *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (RIN: 0991-ZA92)

Dear Secretary Azar:

Kaiser Permanente appreciates the opportunity to respond to the Department of Health and Human Services' (HHS) Request for Information (RFI) on the *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (Blueprint).

Kaiser Permanente commends HHS for taking these first steps toward lower prescription drug prices. As the largest private integrated healthcare delivery system in the United States, the Kaiser Permanente Medical Care Program delivers health care to more than 12.2 million members in eight states and the District of Columbia.¹ Kaiser Permanente is committed to providing high-quality, affordable care and improving the health of our members and the communities we serve. We are deeply concerned about the burden unsustainably high drug prices impose on our members and patients, as well as our ability to carry out this mission.

I. Introductory Comments

Kaiser Permanente's integrated care delivery model gives us a unique and important perspective on many of the issues identified by the Blueprint.² In our experience, pharmaceutical companies continue to raise prices to unaffordable levels, forcing patients and families to choose between paying their rent or mortgage, or paying for their medication. We believe it is time for a new legal and policy landscape for drug pricing that rewards innovation and discoveries, but also provides medicines at prices patients and the health system as a whole can actually afford. As the health care system is being held more accountable for results, pharmaceutical companies need to play by new rules, explain their prices and join in efforts to bend the health care cost curve in the right direction.

¹ Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 38 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members.

² For a more comprehensive overview of Kaiser Permanente's prescription drug benefit and purchasing strategy, please read: Levine, Sharon, et al. Kaiser Permanente's Prescription Drug Benefit, *Health Affairs*, March 2000: <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.19.2.185>.

We work every day to provide the safest, most effective care possible, and we see the drug pricing issue from multiple angles due to our integrated model. Our prescription drug benefit and the way we purchase drugs are distinct from most health plans, pharmacy benefit managers (PBMs), and purchasers. Most importantly, the close collaboration of our pharmacist experts and the physicians in the Permanente Medical Groups are primarily responsible for developing Kaiser Permanente's formulary. On an ongoing basis, our pharmacists review and compile a list of drugs, then our physician experts review the evidence associated with each drug, and make recommendations to pharmacy and therapeutics (P&T) committees primarily composed of Permanente physicians. Our physicians trust a formulary developed by their peers and choose to prescribe from it in an overwhelming majority of cases, which can limit the financial impact of nonformulary prescribing on patients. Physicians may override the formulary when they feel it is medically necessary.

Kaiser Permanente also has a different approach to drug purchasing and price concessions than most other health care stakeholders. We generally negotiate directly with and purchase from pharmaceutical companies instead of outsourcing these functions to third-party PBMs. We prefer to negotiate discounts on prices upfront, but also seek some retrospective rebates. In part, because we are able to buy in bulk, but more importantly because our physicians have a high degree of confidence in our formulary, we can drive market share among similar products. Thus, Kaiser Permanente can often negotiate better price concessions with pharmaceutical companies than other purchasers. Our ability to obtain discounts, however, is still severely constrained by certain laws and pharmaceutical industry practices that we identify and discuss throughout the remainder of our comments.

While Kaiser Permanente has some unique advantages in securing price concessions that benefit our members and purchasers, we are not immune from the crippling burden that high prescription drug prices impose on the health care system. Our power to negotiate is limited by the pharmaceutical industry's nearly unfettered discretion to set excessive prices and to raise them multiple times during the year. Unfortunately, over the past few decades, many well-intentioned laws have exacerbated dysfunction in the market by strengthening and protecting the industry's ability to set prices at will. Today's complex systems for drug purchasing and payment have grown out of efforts to manage this underlying problem. Until the pharmaceutical industry's ability to price arbitrarily is meaningfully restrained by a more functional market, prices will remain unsustainably high.

HHS's Blueprint should serve as an opportunity for federal policymakers to refocus the debate about drug pricing on the underlying causes of the problem. We hope your findings lead to a broad federal effort to revisit relevant laws. This issue deserves sustained attention and intensive study that the Administration and Congress are uniquely situated to provide. Once armed with the right information, policymakers can promote thoughtful reforms that address the causes of high drug prices, not merely the symptoms. We commend HHS for its efforts to address this vexing problem and look forward to working with you as this initiative moves forward.

II. Comments in Response to the Request for Information

A. Increasing Competition

Kaiser Permanente offers the following comments on the Blueprint's proposals and questions related to increasing competition in the pharmaceutical market. We agree that facilitating more robust competition is essential to putting downward pressure on prices. This section of our comments provides information in response to your requests related to biosimilar and generic competition, Risk Evaluation and Mitigation Strategies (REMS), interchangeability, and state pharmacy laws. In addition, we encourage the Administration to consider actions and policies that would address pharmaceutical industry abuses of intellectual property and exclusivity protections that block generic competition.

Patents & Exclusivity

Intellectual property and market exclusivity incentives—granted by the US Patent and Trademark Office and the Food and Drug Administration (FDA), respectively, as well as certain international trade agreements—are key drivers of unsustainably high drug prices because they provide brand-name pharmaceutical companies with monopolies that prevent competition from lower-cost generic alternatives. These monopolies give pharmaceutical companies extraordinary discretion to set high prices. In some cases, duration of the monopoly is disproportionate to the added value the drug delivers, enabling pharmaceutical companies to set and maintain high prices without delivering meaningful new benefits to patients. Kaiser Permanente urges the Administration to work with Congress to assess current intellectual property and exclusivity incentives, making regulatory and legislative changes where appropriate to reward true innovation, reflect the potential for improved patient outcomes, and promote affordability.

Patents

Manipulating patents to gain pricing advantages is a pervasive practice across the pharmaceutical industry. Companies apply for a 20-year patent after discovering a compound to develop into a drug. This initial patent, however, is only the beginning. Most patents filed by the pharmaceutical industry protect existing, rather than new, products. About 78 percent of drug-related patents are for drugs already on the market, and additional patents and exclusivity are sought for almost 40 percent of all approved drugs.³ For example, Purdue Pharma protected OxyContin[®] 13 times by obtaining extensions before its original patent expired.⁴ Humira[®]—a drug that brings in \$16 billion a year in sales for AbbVie—is protected by over 100 patents, ranging from protections for attributes of the product to manufacturing processes. This web of overlapping patents, known as a “patent thicket” or “patent estate,” is used to block competition by making it difficult for generic manufacturers to navigate and challenge patents as they try to launch lower-cost versions of drugs.

In many cases, additional patent protection is awarded for incremental changes, rather than meaningful improvements to drugs. The pharmaceutical industry sometimes couples incremental changes with a “product hop,” in which the brand-name company pulls the original version from the market and switches patients to a new version of the drug before patent expiration. Product hops delay generic competition by forcing manufacturers to start over in developing a generic version of a brand-name product. For example, Actavis’s Namenda[®] was introduced as a twice-daily pill to treat Alzheimer’s disease. Before the product’s patent expired, Actavis withdrew Namenda from the market and replaced it with a once-daily formulation (Namenda XR), thwarting the plans of five generic competitors with pending FDA approvals on a twice-daily version.⁵ If the generic manufacturers failed to change their products, they would be blocked from substitution at the pharmacy counter.

Evergreening practices and product hopping, including Actavis’s anticompetitive behavior with Namenda XR, are occasionally invalidated under patent and antitrust laws. Even in the rare cases where these matters are litigated successfully, generic competition can be minimized and entry can be delayed for years, burdening patients, taxpayers, and the overall health system with avoidable costs in the interim. Increased enforcement against unfair trade practices and greater clarity about which abuses are prohibited through administrative or legislative action may help reduce certain anticompetitive practices across the industry.

³ Feldman, R. and Wang, C. (2018) *May Your Price be Evergreen*, University of California Hastings College of Law, available at: <file:///C:/Users/D727253/Downloads/SSRN-id3061567.pdf>

⁴ *Id.*

⁵ Levy, Mark S. (2017) Big Pharma Monopoly: Why Consumers Keep Landing on "Park Place" and How the Game is Rigged, *American University Law Review*: Vol. 66 : Iss. 1, Article 6, available at: <https://pdfs.semanticscholar.org/2133/d9922d9872caae0b511ad718a5c9c84b2a75.pdf>

The lack of competition created by these abuses delays and inhibits Kaiser Permanente’s ability to negotiate price concessions for our members. Policymakers should reevaluate how patent incentives influence the market and consider changing current law that is being abused, gamed, or is yielding limited value relative to the cost. For example, President Trump’s Fiscal Year 2019 Budget Proposal suggested the Administration is interested in curbing anticompetitive “pay-for-delay” arrangements—a tactic used by brand-name companies during patent litigation to offer potential generic competitors something of value to delay market entry; the brand companies thus maintain their pricing power. Kaiser Permanente encourages the Administration to increase enforcement against pay-for-delay schemes and to work with Congress to clarify laws as necessary to ban these agreements completely.

Kaiser Permanente also encourages HHS to work with Congress to explore ways to account for taxpayer investments in pharmaceutical research and development as the Administration reevaluates patent and exclusivity incentives. Taxpayer investments, such as grants through the National Institutes for Health (NIH), are often crucial to drug development. NIH-funded studies led to the approval of 210 new drugs between 2010 and 2016, investing over \$100 billion of taxpayer money in those medicines.⁶ At minimum, there should be more transparency about taxpayer-funded research support for the development of FDA-approved products so the public can trace how its investments compare to the prices ultimately charged by the industry. For egregious patent abuses, the Administration might consider whether it is possible to intervene through existing mechanisms available under the *Bayh-Dole Act* (Pub. L. 96-517) or 28 U.S.C §1498 to stop unfair exploitation of taxpayer-funded research.

Exclusivity

FDA also grants market exclusivity for new drugs, to provide a guaranteed period during which generic or biosimilar competition will not be approved for marketing, regardless of the branded product’s remaining patent life. Under the *Drug Price Competition and Patent Term Restoration Act* (Pub. L. 98-417), commonly known as the *Hatch-Waxman Act*, newly approved drugs get five years of exclusivity. The *Biologics Price Competition and Innovation Act* (BPCIA), enacted as part of the *Affordable Care Act* (Pub. L. 111-148), grants 12 years of exclusivity for biologics. As with patents, these initial exclusivity periods are often extended, including under the *Orphan Drug Act* and *Best Pharmaceuticals for Children Act*.

Under the *Orphan Drug Act* (Pub. L. 97-414), drugs approved for rare diseases earn a separate seven years of exclusivity (for the rare indication) that can run concurrently with other exclusivities. In 2016, 41 percent of new drug approvals included an orphan designation.⁷ Orphan drugs are often among the biggest revenue producers in the pharmaceutical industry. In some cases, pharmaceutical companies have been able to game orphan drug exclusivity by seeking indications for narrow populations and repurposing the drug for additional approvals. For example, Gleevec[®]—a cancer drug that earned Novartis \$4.5 billion in revenue in 2015—has received nine orphan approvals.⁸ We applaud Congress and HHS for beginning to address these abuses in the *FDA Reauthorization Act of 2017* (FDARA) (Pub. L. 115-52) by limiting the circumstances under which existing drugs can obtain orphan exclusivity. However, as trends toward personalized and precision medicine continue, we encourage policymakers to reassess the costs and benefits of incentives offered under the *Orphan Drug Act* to ensure an appropriate balance between innovation and affordability.

⁶ Cleary, E. et al. (2018) Contribution of NIH Funding to New Drug Approvals 2010-2016, National Academy of Sciences, available at: <http://www.pnas.org/content/early/2018/02/06/1715368115>

⁷ Kesselheim, A. et al. (2017) Determinants of Market Exclusivity for Prescription Drugs in the United States, *JAMA Intern Med.* 177(11):1658-1664, available at: <https://www.ncbi.nlm.nih.gov/pubmed/28892528>

⁸ Hillkirk, J. et al. (2017) Drugs for Rare Diseases have Become Uncommonly Rich Monopolies, *NPR*, available at: <https://www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies>

Under the *Best Pharmaceuticals for Children Act* (Pub. L. 112-144), companies can earn an additional six months of exclusivity for completing pediatric trials on their products. Of nearly 200 drugs awarded pediatric exclusivity between 1998 and 2012, only 57 percent resulted in new or expanded pediatric indications, some of which have questionable clinical utility.⁹ Pharmaceutical company revenue resulting from pediatric exclusivity exceeds the cost of performing the required trials by an average \$134 million per drug, a profit ratio of ten-to-one.¹⁰ While facilitating pediatric trials is a worthwhile policy goal, HHS and Congress should consider whether there are more narrowly tailored ways to achieve the same objective while also encouraging competition to lower drug prices.

Kaiser Permanente also believes that the 12-year exclusivity period for biologics under the BPCIA delays biosimilar competition for too long. Biologic drugs are often among the most expensive on the market, sometimes priced at hundreds of thousands of dollars per course of treatment. Timely access to more affordable biosimilars would help provide relief to patients, the health care system and taxpayers. Some estimates suggest that reducing the biologic exclusivity period to seven years could save nearly \$7 billion over ten years.¹¹ It bears reiterating that the issue is not just about the savings; but also about getting effective new treatments developed and on the market so patients can use them. Reducing the exclusivity window would require a statutory change, so we encourage HHS to work with Congress to shorten the period and facilitate a more competitive biologics market.

Finally, the Administration should examine the frequent misuse of international trade agreements to lock in to international agreements extensions of intellectual property protections. For example, the United States was required to extend industrial patents from 17 years to 20 years in the Uruguay Round Agreements Act of 1994, because international negotiators agreed behind closed doors to increase the patent terms. United States law cannot be changed to return patent terms to 17 years without abrogating that treaty. Similarly, the pharmaceutical industry aggressively sought to include in the Trans Pacific Partnership the excessive 12-year market exclusivity for biologics that was included in the Affordable Care Act to make it much more difficult to modify United States law in the future. We urge the Administration to be wary of private interests, such as the pharmaceutical industry, to use international agreements to undermine Congress's ability to modify intellectual property laws when abuses or imbalances become apparent.

REMS Abuses

Kaiser Permanente appreciates HHS's ongoing attention to abuses of Risk Evaluation and Mitigation Strategies (REMS) by the pharmaceutical industry. The *FDA Amendments Act of 2007* (Pub. L. 110-85) authorized FDA to implement REMS programs that require or allow pharmaceutical companies to impose safety requirements on drugs with known risks. As part of REMS programs, FDA can require "elements to assure safe usage" (ETASU), such as special certification for dispensing, prescriber training, and dispensing limited to certain health care settings. ETASU requirements are sometimes leveraged by pharmaceutical companies to restrict a drug's distribution by erecting barriers to market entry that does not result in safety benefits for patients. While we strongly support the REMS program's goal of improving safety, the program must be updated to ensure pharmaceutical companies cannot "game" the process to block generic competition or artificially restrict distribution pathways to maintain unreasonably high prices.

⁹ Wharton, G. et al. (2014) Impact of Pediatric Exclusivity on Drug Labeling and Demonstrations of Efficacy, *Pediatrics* 134(2):e512-8, available at: <https://www.ncbi.nlm.nih.gov/pubmed/25022732>

¹⁰ Kesselheim, A. et al. Determinants of Market Exclusivity for Prescription Drugs in the United States, *JAMA Intern Med.* 2017;177(11):1658-1664. doi:10.1001/jamainternmed.2017.4329

¹¹ Policy Proposal: Reducing the Exclusivity Period for Biological Products, PEW Charitable Trusts, available at: <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2017/09/policy-proposal-reducing-the-exclusivity-period-for-biological-products>

Access to Samples

FDA requires generic manufacturers to demonstrate bioequivalence to the reference brand-name product as part of the generic approval process. To conduct bioequivalence testing, the generic manufacturer must obtain samples of the brand-name product. Generic manufacturers, however, are not always authorized to receive drugs subject to a REMS with ETASU requirements, and therefore cannot access samples from wholesalers. Some brand-name pharmaceutical companies use REMS to justify withholding samples that generic manufacturers need for FDA approval, causing delays in generic competition.

FDA's ability to compel the brand-name company to turn over samples is limited. Recently, FDA posted a list of brand-name drugs where a request for access to a sample for generic development was blocked. This list revealed over 50 medicines for which generic alternatives have been delayed due to REMS abuses.¹² To resolve this problem, Kaiser Permanente supports the *Creating and Restoring Equal Access To Equivalent Samples Act* (CREATES Act) (S. 974/H.R. 2212), which creates a specific cause of action against brand-name companies that fail to provide generic manufacturers with samples on reasonable terms. The nonpartisan Congressional Budget Office (CBO) estimated that the CREATES Act would reduce federal health spending by \$3.8 billion over ten years by increasing generic competition. Private payers would also save significantly. In the absence of a legislative fix to this problem, we encourage FDA to exercise all authority it has over the REMS program to curb abuses.

Restricted Distribution & Contracts

Brand-name pharmaceutical companies also use REMS to enter into restrictive contracting arrangements that make it impossible for providers and pharmacies to acquire drugs at a reasonable price. Kaiser Permanente would support granting FDA authority to review of manufacturer-imposed restrictions and to develop policies that would facilitate greater, more affordable access to such products. For example, some companies have used ETASU requirements to contract exclusively with a limited number of specialty pharmacies, protecting high prices by controlling access to their products.

Even though Kaiser Permanente's National Specialty Pharmacy has extensive experience complying with REMS and ETASU requirements, some pharmaceutical companies do not permit us to acquire and dispense restricted drugs within our system.¹³ Not only do these restrictions allow pharmaceutical companies to burden patients with higher prices, they also inhibit our ability to implement safety checks, monitor quality and coordinate care because information related to the REMS drug will not be captured automatically in our electronic health records when care is provided outside our integrated system.

Kaiser Permanente recommends that FDA require manufacturers to explicitly permit health systems or pharmacies able to demonstrate they meet or exceed REMS requirements to access and dispense REMS drugs to their patients. We would also support new FDA guidance or regulations clarifying that REMS programs cannot arbitrarily restrict distribution to dispensers that can meet appropriate criteria. These modifications would help facilitate lower drug costs through competitive pricing and national purchasing negotiations. It would also leverage existing systems and tools designed to enhance patient safety and continuity of care.

Generic & Biosimilar Competition

Kaiser Permanente strongly supports efforts to increase generic competition and market penetration, especially for biologics. Studies suggest that the presence of at least two or three generic competitors in a

¹² Reference Listed Drug (RLD) Access Inquiries, U.S. Food & Drug Administration, available at: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>

¹³On December 22, 2009, Kaiser Permanente submitted a Citizen's Petition to FDA under 21 C.F.R.§10.30 regarding the REMS Program.

market can lead to meaningful reductions in price,¹⁴ which generally reflects Kaiser Permanente’s experience negotiating discounts with pharmaceutical companies. We applaud ongoing efforts by FDA and Congress to reduce the backlog of generic drug applications and increase approvals for small molecule drugs, while preserving important quality safeguards. More must be done, however, to facilitate robust biosimilar competition that exerts downward pressure on biologic prices.

Interchangeability

Biologics and specialty drugs are the fastest growing component of prescription drug spending. Treatment costs for some biologics can be hundreds of thousands of dollars per year, imposing crippling costs on patients and the health system. Both increased uptake and escalating prices for biologics encouraged Congress to enact an FDA approval pathway for lower-cost biosimilar alternatives through the BPCIA. Biosimilars are highly similar variants of reference biologic drugs that show no meaningful clinical difference in terms of safety, purity and potency. Biosimilars must meet high evidentiary thresholds to establish either “biosimilarity” or “interchangeability.” To be interchangeable, the product must demonstrate to FDA that it produces the same clinical result as the reference product in any given patient—a very high bar.

Fostering a robust market for biosimilar competition is essential to lowering prices. FDA has approved only 11 biosimilars to date; only three are available to patients due to patent complications.¹⁵ By contrast, 40 biosimilar products have been approved to date by the European Commission.¹⁶ We strongly urge FDA to do more to facilitate biosimilar product development and market entry. On January 1, 2017, FDA issued draft guidance outlining proposed factors it will consider in determining interchangeability, but has not finalized its guidance. Despite these steps, there are no approved interchangeable biosimilars in the United States. FDA must do more to create certainty and predictability for biosimilar manufacturers seeking interchangeability designations, while still ensuring that interchangeability determinations are guided by science and not prejudged categorically.

State Pharmacy Laws

Some state laws also create barriers to substituting biosimilars for reference biologics, hampering competition and intensifying the market dysfunction that drives drug prices upward. For example, many states have laws that place unreasonable restrictions on pharmacists substituting biosimilars, such as unnecessary notice and double-checking requirements that apply even when the high bar for interchangeability is met.¹⁷ These laws could limit the positive effects of any effort by FDA clarify interchangeability standards and create certainty in the biosimilar market. When a biosimilar can satisfy requirements for an interchangeability designation, the law should allow substitution as it does for small molecule generic drugs.

Provider Education on Biosimilars

Kaiser Permanente appreciates HHS’s interest in supporting further provider education about biosimilars, which is a high priority for our Permanente Medical Groups and pharmacy operations. Kaiser Permanente has been successful at encouraging clinically appropriate utilization of biosimilars in the limited cases where such therapies are available. Our success is largely attributable to physician confidence in our

¹⁴ Dave, C. et al. (2017) Prices of Generic Drugs Associated with Number of Manufacturers, *New England Journal of Medicine* 377:2597-2598, available at: <https://www.nejm.org/doi/full/10.1056/NEJMc1711899>

¹⁵ Biosimilar Product Information, U.S. Food & Drug Administration, available at: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580432.htm>

¹⁶ Hamzah Aideed, Guest Column, *Biosimilar Development*, April 10, 2018

¹⁷ There are many state-level legislative efforts related to substitution for biologics, including the option for prescribers to specify, “dispense as written.” See: <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx> for more information on state efforts regarding substitution.

formulary, since Permanente physicians play a leading role in its development alongside our pharmacy experts. Kaiser Permanente also maintains a team of research pharmacists to answer physician questions and disseminate information about biosimilars and other drugs through bulletins, webinars, and presentations. These resources give our providers the tools and information necessary to appropriately switch patients onto biosimilar versions of products such as Inflectra[®] and Renflexis[®] (biosimilars for Remicade[®]) and Zarxio[®] (biosimilar for Neupogen[®]).

Timely access to data is crucial to helping providers evaluate when biosimilars are appropriate for their patients. We appreciate FDA's recent efforts to make more information about biosimilars, including review materials, available to the public through its website. The relatively robust data available for both Inflectra and Zarxio provided the information our physicians and pharmacy researchers needed to evaluate whether switches were appropriate for individual patients. Unfortunately, review materials are not always made public, particularly for any product not subject to Advisory Committee review or not the first approved biosimilar in its class. Even when such resources are public, posting is often delayed, sometimes by over a year. Moving forward, we encourage FDA make review materials for all approved biosimilars available on its website within two months of approval.

Kaiser Permanente has also established internal policies that significantly restrict marketing and detailing by pharmaceutical companies in our facilities and to Permanente physicians.¹⁸ Because of the resources we provide our physicians, they have sources of reliable, unbiased information about drug products and less need to rely on information provided by pharmaceutical representatives, whose primary motivation is to increase sales.

B. Better Negotiation

Kaiser Permanente offers the following comments on the Blueprint's proposals and questions related to giving drug purchasers more leverage to negotiate with pharmaceutical companies. Some of the policy changes the Blueprint identifies could help level the playing field between pharmaceutical companies and health plans as we work to get lower costs for our members. We offer the following responses to your requests related to the Medicaid Drug Rebate Program, Medicare Parts B and D, emerging financing models for pharmaceuticals, and foreign trade.

Medicaid Drug Rebate Program

Kaiser Permanente encourages HHS to consider reforms to the Medicaid Drug Rebate Program (MDRP) that would enable private health plans and other purchasers to negotiate lower prices with pharmaceutical companies. The MDRP provides statutorily defined rebates on outpatient prescription drugs to state Medicaid programs. While the intent of the program is to help ensure that Medicaid pays the lowest price, the MDRP has unintended consequences that lead to higher prices. Without meaningful changes, the MDRP will continue to stymie payers' efforts to negotiate more affordable drug prices for our members.

Best Price

Enactment of the MDRP dramatically changed pharmaceutical companies' incentives for negotiating with health system purchasers on outpatient drug discounts. Under the program, the rebate paid to the state on brand-name drugs is the greater of either a fixed percentage of the Average Manufacturer Price (AMP)¹⁹ or the difference between AMP and the "best price" paid by *any* purchaser. Because of how rebates are

¹⁸Kaiser Permanente limits detailing to formulary products. We also limit access, require registration ad audit content. Those who violate our policies are barred from our facilities.

¹⁹The AMP is the average price wholesalers pay manufacturers for drugs sold to retail pharmacies, reflecting discounts and other reductions.

calculated, any discounts pharmaceutical companies give to health plans have significant implications for the rebates they will have to provide states for millions of people enrolled in Medicaid.

To reduce their rebate liability to state governments, pharmaceutical companies will try to prevent the spread between best price and AMP from exceeding the statutory discount. The fixed percentage used to calculate Medicaid rebates varies depending on the drug. For brand-name drugs, the fixed percentage is generally 23.1 percent. Alternatively, the best price is the lowest price paid for a brand name drug to *any* purchaser, reflecting all discounts, rebates and other pricing adjustments. There are several exemptions from best price calculations, including prices paid by the Department of Veterans Affairs, the Department of Defense, 340B hospitals, and prices negotiated by private plans under Medicare Part D.

When pharmaceutical companies negotiate discounts greater than 23.1 percent of the AMP, best price rules will force them to sell the same drugs to Medicaid at the same price, increasing rebate payments for brand drugs. This incentive affects discount negotiations on numerous drugs due to the breadth of the MDRP. To have their products covered under Medicaid, pharmaceutical companies enter into national agreements with HHS to provide rebates. In exchange for these rebates, state Medicaid programs agree to cover all the company's drugs. Approximately 600 pharmaceutical companies have entered into rebate agreements, causing virtually all drugs approved by FDA to receive Medicaid coverage.²⁰ As a result, health plans have found it very difficult to negotiate discounts above 23.1 percent of AMP on most outpatient drugs.

For Kaiser Permanente, best price has created an artificial price floor that we encounter almost every day in our efforts to negotiate more affordable outpatient drug products for our members. We urge HHS to work with Congress to eliminate the "best price" component and develop a long-term solution that would tear down the barriers to negotiation while holding states harmless by increasing the flat rebate. While eliminating best price or imposing higher rebates would require a statutory change, HHS could explore whether demonstration projects or waiver authorities could be used to experiment with new best price exemptions, particularly in the context of value-based contracts between payers and pharmaceutical companies (*see* "Value-Based Contracts" on p. 13).

State Medicaid Formulary Trends

State Medicaid programs are also under pressure to reduce drug spending due to rising prices. As a result, some states look to increase their leverage in supplemental rebate negotiations by seeking waivers to implement closed formularies, imposing requirements on managed care organizations (MCOs) that contract with Medicaid, or using preferred drug lists (PDLs). The Administration must take steps to ensure that any efforts to help states negotiate higher supplemental rebates do not inadvertently inhibit payers' ability to negotiate deeper discounts with pharmaceutical companies or interfere with the ability of physicians to prescribe the most appropriate drug.

Supplemental rebate agreements allow states to negotiate additional rebates with pharmaceutical companies beyond the rebates already required under the MDRP. A few states, including Massachusetts and Arizona, have asked if the Administration would be willing to waive Medicaid requirements that prohibit use of closed formularies so they can negotiate better supplemental rebates. Nearly all states use PDLs that list preferred drugs not subject to prior authorization. Pharmaceutical companies are often willing to pay the state a supplemental rebate to ensure their product makes it onto the preferred list, and would almost certainly pay higher rebates to ensure their products are not excluded from Medicaid.

²⁰ Medicaid Drug Rebate Program, Centers for Medicare & Medicaid Services, available at: <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>

Some states have also sought to impose statewide formularies or “uniform” PDLs on MCOs as a mechanism to drive-up supplemental rebates even further. These state policies require Medicaid MCOs to adopt the state’s formulary or requirements for designating preferred and non-preferred drugs. These policies could have the unintended consequence of increasing utilization of brand-name products with higher rebate potential at the expense of lower-cost alternatives and generics. MCOs and their enrollees also do not share in the cost-savings from supplemental rebates provided to the state. As a result, MCOs may have to give preferential treatment to drugs that will be more expensive for our members; this also creates an environment where providers are unable to prescribe the most appropriate drug for their patients.

Kaiser Permanente is concerned that further movement toward statewide formularies or uniform PDLs, if done in an overly rigid manner, could impede our ability to negotiate productively with pharmaceutical companies. State requirements that give preferential treatment to brand-name products threaten the remarkably high generic penetration we achieve on our formulary, forcing us to utilize more expensive drugs even though we are not able to get the same discounts the state gets through supplemental rebates. Such an approach would also hamper our overall ability to negotiate discounts with pharmaceutical companies. Our ability to negotiate deeper discounts is closely connected to utilization patterns for the drugs on our formulary. Changes in utilization caused by state requirements could have a direct, negative impact on our ability to purchase drugs at the most affordable price for our members.

We urge HHS to work to avoid these unintended consequences as it considers State Plan Amendments, waiver applications, or potential demonstration programs that would allow states to make further changes to their Medicaid formularies. While such policies may result in savings to states, we are concerned those savings would be achieved at the expense of enrollees in other health plans. States should, however, be able to pursue negotiations with manufacturers of new, single-source innovator drugs. MDRP requirements often leave states without the power to negotiate a price that includes clinical criteria for patients to access new drugs. Therefore, Kaiser Permanente also encourages HHS to support state proposals that increase flexibility in supplemental rebate negotiations for these products.

Medicare Part B

Kaiser Permanente appreciates HHS’s focus on unsustainably high costs under Medicare Part B’s drug benefit. Medicare Part B covers drugs administered by physicians and other health care professionals in outpatient settings, such as infusible or injectable drug products. Part B drugs are among the most expensive for patients and taxpayers. In 2015, Medicare and its beneficiaries spent \$26 billion on Part B drugs. Since 2009, Part B drug spending has grown by an average of nine percent each year.²¹ Slowing price growth in this area is crucial to increasing affordability for Medicare enrollees, the overall health system, and taxpayers. We encourage HHS to revisit Part B’s reimbursement structure and explore how to better manage the Part B drug benefit.

Average Sales Price

While Kaiser Permanente does not bill a large volume of drugs to Medicare Part B (as we participate in Medicare primarily through the Medicare Advantage program), we strongly encourage HHS to examine Part B reimbursement due to its effect on drug prices across the health care system. The *Medicare Prescription Drug, Improvement, and Modernization Act* (Pub. L. 108-173) directs Medicare to reimburse physicians and suppliers for most Part B drugs, based on the drug’s Average Sales Price (ASP) plus a six percent add-on payment. ASP reflects the average price of a drug, including all rebates, discounts and concessions. The ASP-based formula is flawed and long overdue for reform.

²¹ Part B Drugs Payment Systems (2017), Medicare Payment Advisory Commission, available at: http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_partb_final.pdf?sfvrsn=0

Many stakeholders, including the nonpartisan Medicare Payment Advisory Commission (MedPAC), have noted that the six percent add-on payment creates perverse incentives for physicians to steer patients toward more expensive drugs.²² The six percent add-on payment is meant to reimburse physicians for storage, handling and other administrative costs associated with Part B drugs. There does not appear to be a sufficient policy justification for tying payment for these services to the underlying cost of a drug. Indeed, basing the payment on the price set by the manufacturers both undermines economically neutral drug selection by physicians and rewards price inflation by manufacturers.

In addition, ASP-based payment can discourage manufacturers from providing discounts, rebates and other price concessions to purchasers. Many physician practices use a “buy-and-bill” model: They buy Part B drugs for their offices and are later reimbursed by Medicare at the ASP + 6% rate, which is different from the purchase price. When ASP declines, the difference between the price physicians pay to acquire the drugs and what Medicare reimburses narrows. In some cases, Medicare reimbursement may dip below what certain physicians pay for the drugs. To avoid creating a disincentive for physicians to purchase their products, pharmaceutical companies try to prevent ASP from falling below a certain threshold so they can maintain an ideal spread between acquisition costs and reimbursement. This creates an artificial “ASP floor” for discounts on Part B drugs.

Kaiser Permanente does not use the buy-and-bill model for purchasing Part B drugs. Rather, we negotiate directly with pharmaceutical companies as we do for other drug products. Despite our superior negotiating leverage compared to most other Part B drug purchasers, the ASP floor greatly inhibits our ability to procure discounts we might otherwise obtain, as price reductions to Kaiser Permanente (or other effective purchasers) would result in a lower ASP.

We recommend modifying Part B’s reimbursement structure to reimburse physicians for the costs they incur in acquiring Part B drugs up to a capped amount coupled with a flat add-on payment to cover handling and administration costs. Cost-based reimbursement would remove the industry’s disincentive to negotiate discounts on Part B drugs. Capping reimbursement would also limit the extent to which pharmaceutical companies could arbitrarily increase what they charge physicians in response to this policy. If they raise prices too high, they will not be able to maintain a spread between acquisition costs and reimbursement that enables them to maximize sales to physicians. A flat add-on fee – even one that largely preserved the current average overall reimbursement to physicians – would remove perverse incentives for physicians to prescribe more expensive drugs. HHS should consider testing these proposals through a demonstration program before moving to a broader scale.

Improved Management of the Part B Drug Benefit

Kaiser Permanente also appreciates HHS’s interest in increasing management of the Part B drug benefit by reforming the Competitive Acquisition Program and by moving certain drugs from Part B to Part D. We believe broader use of utilization management tools for Part B drugs, including by government payers, could have a systemwide impact on affordability. While we support the spirit of these proposals, they could be complex, difficult to administer, and disrupt care for patients if not implemented in a careful and deliberate way.

If HHS chooses to move drugs from Part B to Part D, we recommend starting with a small-scale demonstration project that tests the model with a limited set of Part B drugs currently dispensed at the pharmacy counter. A broader transition could cause disruptions in care for patients who are administered these drugs in physician offices and other clinical settings. Once appropriate drugs are identified, the

²² Medicare Part B Drug Payment Policy Issues (2017), Medicare Payment Advisory Commission, available at: http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0

Administration should consult stakeholders, particularly payers and pharmacists, about the resources that would be required to transition the drugs to Part D.

HHS also must take steps to shield patients from potential unintended consequences of shifting drugs from Part B to Part D, including access barriers and higher cost-sharing. As the Blueprint notes, not all Medicare beneficiaries are enrolled in Part D plans. Removing certain drugs from Part B could cause some patients to lose affordable access to medication. HHS may need to exempt those patients or find another mechanism to ensure access for beneficiaries without Part D coverage.

Part B and Part D also have different cost-sharing structures, which could cause some beneficiaries to experience out-of-pocket cost increases. Under Part B, patients pay a 20 percent coinsurance, while Part D cost-sharing varies as the beneficiary utilizes drugs. In the initial period, beneficiaries pay 25 percent of costs. Once the initial coverage limit is reached, beneficiaries move into the coverage gap (“donut hole”), where cost-sharing remains at 25 percent thanks to recent changes under the *Bipartisan Budget Act of 2018* (Pub. L. 115-123). After the catastrophic coverage threshold, beneficiary cost-sharing is five percent. Private plans can vary cost-sharing so long as they remain within certain parameters. Depending on how the Part D plan covers the drug, beneficiaries could therefore be forced to pay more out-of-pocket than they did under Part B.

It is important to recognize that supplemental insurance policies such as Medigap plans that many beneficiaries use to help defray cost-sharing under Part B generally do not apply to cost-sharing under Part D. Therefore, beneficiaries who use supplemental coverage to help pay for expensive Part B drugs might be exposed to significantly higher cost-sharing after a drug transitions from Part B to Part D.

The affordability implications of transitioning drugs from Part B to Part D must be thoroughly evaluated before HHS moves forward with policy development to avoid surprising unsuspecting patients with increased out-of-pocket costs. We agree that creating a list of drugs that could be transitioned from Part B to Part D is the right place to start. HHS should also conduct a beneficiary impact analysis, examining potential access and cost-sharing issues. Stakeholders, including patients, must have an opportunity to comment and work with HHS to determine whether it is possible to transition certain drugs from Part B to Part D in a way that will give payers more negotiating ability without disrupting patient care and affordability.

Moving drugs from Part B to Part D may also have cost implications for taxpayers. Such a shift could push beneficiaries through the coverage gap phase more rapidly, shifting costs onto the federal government in the catastrophic phase, where the federal government provides reinsurance for 80 percent of Part D drug costs. If beneficiaries reach the catastrophic phase faster, the government will be liable for 80 percent of *all* the beneficiary’s Part D costs earlier than it otherwise would be. HHS should assess whether these additional costs to taxpayers are outweighed by the affordability benefits to patients.

Medicare Part D

Kaiser Permanente strongly supports increasing flexibility under Medicare Part D as a mechanism for helping payers negotiate lower prices for our members. Several proposals in the Blueprint and President Trump’s fiscal year budget proposals would help accomplish this goal, including proposals to revisit Part D’s therapeutic classes and allow plans to address price increases for sole-source generics during the plan year. We believe these proposals can be implemented in a manner that does not impede beneficiary access to clinically appropriate medication.

Formulary Adjustments for Sole-Source Generic Price Spikes

Kaiser Permanente supports allowing Part D plans to adjust formularies during the plan year when a sole-source generic drug increases its price. Under current law, Part D plans cannot make negative formulary

changes during the plan year. However, sole-source generic manufacturers often have discretion to increase prices dramatically without warning. For example, when Turing Pharmaceuticals acquired marketing rights to pyrimethamine (the generic version of Daraprim[®]), it abruptly increased the price from \$13.50 to \$750 per pill. Even in less dramatic cases, Kaiser Permanente can sometimes get more favorable pricing from the brand-name company when the generic manufacturer increases its price. Having the flexibility to make formulary adjustments in response to price spikes would help achieve cost savings because plans could push back against arbitrary and unpredictable price increases.

Part D Therapeutic Categories & Classes

Current Part D formulary requirements sometimes inhibit plans' ability to negotiate price discounts for our members. For example, Medicare requires plans to cover at least two drugs per therapeutic class and "all or substantially all" FDA-approved drugs in the six protected classes.²³ Modifying these requirements could help achieve lower drug prices without preventing access to medically necessary drugs. Even if plans are given more formulary flexibility, Medicare will still require Part D plans to meet "clinical appropriateness" standards to help patients access those drugs. CMS should use its authority under current law to apply protected status only when other Medicare requirements are not sufficient to ensure access to a range of therapies. This change would enhance plans' ability to negotiate discounts while protecting patient access.

HHS should also consider a broader reassessment of Part D's therapeutic categories and classes. The *Medicare Prescription Drug Improvement and Modernization Act* (MMA) (Pub. L. 108-173) requires Part D plans to include two drugs within each class or unique category of covered drugs. CMS contracts with the U.S. Pharmacopeia (USP) to develop the categories and classes by issuing Model Guidelines. The MMA also gives CMS authority to work with USP to revise the categories and classes on a routine basis to accommodate new drugs or changes in uses of currently covered drugs. The Model Guidelines are typically reviewed once every three years. The most recent version includes 48 categories and 154 classes²⁴, which is too granular and leaves Part D plans with few tools to manage overpriced drugs with limited clinical benefits.

CMS should conduct a comprehensive review of Part D categories and classes, identifying potential areas for consolidation. By consolidating categories, CMS would provide payers with more flexibility to make appropriate safety and efficacy determinations and leverage to negotiate discounts with pharmaceutical companies.

Payment & Financing Models for Pharmaceuticals

Kaiser Permanente appreciates HHS's interest in facilitating value-based payment and other unique financing models with pharmaceutical companies. These emerging models could be helpful in limited contexts, with appropriate changes in law. Most importantly, lawmakers must find a way to exempt discounts negotiated under these contracts from best price and ASP calculations. Even with these exemptions, value-based payment will not have a meaningful impact on prices without significant changes to the underlying laws that would improve market conditions and thus restrain pharmaceutical companies' ability to price arbitrarily.

Value-Based Contracts

Under current law, Kaiser Permanente's ability to engage in meaningful value-based contracts with pharmaceutical companies is extremely limited. Currently, we have two value-based contracts, neither of

²³ The six protected classes include immunosuppressants, antidepressants, antiretrovirals, antipsychotics, anticonvulsant agents, and antineoplastics.

²⁴ *Final Report: USP Medicare Model Guidelines v7.0*, U.S. Pharmacopeia, available at: http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/2017-02-06_final_report_uspmmg_v7_0_rev170206.pdf

which appreciably decreases our pharmaceutical spend. Under a standard value-based contract, the payer and pharmaceutical company agree on outcome measures to assess the drug's performance. The payer will then track data across the relevant patient population to determine whether outcome measures are satisfied. Ideally, pharmaceutical companies should reimburse payers and patients when drug products do not perform as promised, especially for newer drugs whose efficacy is not well-understood outside highly controlled clinical trial settings. However, due to the limits that "best price" and ASP place on discounts, pharmaceutical companies are not willing to accept sufficient risk to make these contracts worth the considerable resources required to execute them.

We also recommend that HHS expand best price and ASP contracting exclusions beyond orphan drugs, which are generally indicated to treat rare diseases. Thus, orphan drug patient populations are often too small for plans to reliably track outcomes. HHS should instead allow such exclusions for any drug and let the private market dictate which products are most amenable to these arrangements. We also encourage HHS to explore ways to incorporate physician voices into value determinations to help align any value-based framework with true clinical value and patient care needs.

Wider use of value-based contracts is not enough to make significant long-term progress against high drug prices. First, these contracts do not actually lower list prices. Rather, they provide payers and patients a mechanism to get some money back if a therapy fails. There is also no guarantee that pharmaceutical companies would be willing to enter into meaningful value-based contracts with payers. Other changes in law suggested throughout our comments may be necessary to increase payers' leverage and ability to keep pharmaceutical companies at the negotiating table.

Long-Term Financing

Some economists have proposed long-term financing models as a way to ensure patients can access extremely expensive medications. However, we think these models are a step in the wrong direction. Kaiser Permanente is concerned that increased use of long-term financing models will create a reimbursement infrastructure that makes it easier for pharmaceutical companies to launch products at outrageously high prices. Mortgaging our health plan future will also hinder the ability to afford tomorrow's breakthrough therapy and guarantees the need for further premium hikes. Policymakers and regulators should instead focus on solutions that drive down list price, rather than solutions that accept high prices as inevitable and attempt to work around them.

In rare cases, extended payment terms may be helpful in administering long-term, value-based contracts, so long as such an arrangement does not reflect simply financing high prices over time, shifting today's economic burden to future insured populations. Such arrangements could be appropriate for expensive drugs that are supposed to show durable effects over a long period. New high-price drugs, especially orphan drugs, often have limited clinical and safety data, and most do not have long term data. It is difficult for payers to predict whether these drugs will work and if there are unknown downstream side effects.

Under this type of long-term contract, the payer would make a down payment on the drug, and the patient would be required to complete check-ups during a defined period to assess whether the drug is working as intended. If agreed-upon outcome measures are met, the payer makes an additional installment payment. If not, the pharmaceutical company should bear the risk of loss, since they are primarily responsible for the product's performance. Such contracts, however, face all the same challenges as other types of value-based contracts.

Indications-Based Pricing

Indications-based pricing is another subset of value-based contracting that is likely to produce mixed results. If not carefully crafted, these models could be exploited by pharmaceutical companies to increase

prices when a drug is used among the subset of patients most likely to benefit. Therefore, indications-based pricing could increase patients' out-of-pocket costs and increase payers' net pharmaceutical spending.

As with long-term financing, indications-based pricing models would face the same implementation challenges as value-based contracts.

Foreign Trade

The Blueprint correctly notes that patients in the United States pay considerably more than people in other countries for pharmaceuticals —on average, nearly double what the United Kingdom pays for blockbuster drugs Humira and Xarelto.²⁵ We certainly agree that these disparities in price are grossly unfair to patients and their families.

The problem is overpricing in the United States. Increasing prices in other countries would not result in lower prices here. Manufacturers are not pricing to achieve a fixed revenue target; they are charging whatever the economic conditions in any given market will allow. In fact, fortifying pricing standards or intellectual property standards through international agreements may have the opposite effect, making it more difficult to change domestic policy related to drug pricing. Kaiser Permanente strongly recommends that the Administration work on reforming domestic policies that enable the pharmaceutical industry to arbitrarily dictate price rather than using foreign trade to force other countries to accept higher prices.

C. Lower List Prices

Kaiser Permanente offers the following comments on HHS's proposals and questions related to lowering list prices, specifically, responses to your requests related to limiting drug price growth, increasing transparency, including prices in direct-to-consumer advertisements, and rebates.

Limiting Drug Price Growth

Kaiser Permanente appreciates HHS's interest in exploring mechanisms to limit drug price inflation. Under current law, pharmaceutical companies have considerable discretion to increase list prices arbitrarily. For example, between 2010 and 2015, prices for the 20 most commonly prescribed drugs under Medicare Part D increased at a rate ten times higher than inflation, with average increases of 12 percent each year. Twelve of the top 20 drugs experienced price increases of over 50 percent during the five-year period.²⁶ Price increases of this magnitude are simply unsustainable because they crowd out spending on other public and private priorities.

One effective mechanism for slowing price inflation would be to impose price transparency requirements on Part B and D drugs when their prices increase above a certain threshold, over a defined lookback period. For example, manufacturers would be required to explain increases when they raise prices over a certain amount. In addition, we and other private entities are free to employ contract provisions about price and utilization in negotiations with manufacturers. We commit to certain levels of utilization while the manufacturer agrees to limit price increases over a specified length of time (our initial proposed threshold is the average Consumer Price Index (CPI) or four percent, whichever is less, over a year-long lookback period).

²⁵ Kamal, R. and Cox, C. (2017) What are the Recent Forecasted Trends in Prescription Drug Spending?, Kaiser Family Foundation, available at: https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-average-price-xarelto-u-s-double-price-united-kingdom_2017

²⁶ *Manufactured Crisis: How Devastating Drug Price Increases are Harming America's Seniors*, Minority Office, U.S. Senate Homeland Security & Governmental Affairs Committee, available at: <https://www.hsgac.senate.gov/imo/media/doc/Manufactured%20Crisis%20-%20How%20Devastating%20Drug%20Price%20Increases%20Are%20Harming%20America's%20Seniors%20-%20Report.pdf>

Medicare is already required to cover certain drugs under Part B and Part D, so utilization is mandated. But if Medicare had additional tools to affect price fluctuations when a drug benefits from such mandatory inclusion, such as transparency and limits on increases, price escalation could slow.

This proposal would be most effective if implemented alongside other proposals that would put downward pressure on list and launch prices. Otherwise, pharmaceutical companies may have an incentive to launch products with few competitors at higher prices to make it easier to take sizeable dollar amount price increases while remaining under the inflationary thresholds.

Transparency

The lack of transparency and accountability for initial prices and price increases are key drivers of dysfunction in the pharmaceutical market in the United States. Many states have proposed drug pricing transparency laws and some have enacted them, including California, Oregon, Vermont, and Nevada. The *FAIR Drug Pricing Act* (S. 1131/H.R. 2439), bipartisan legislation that would require pharmaceutical companies to be more transparent in their pricing, is also pending at the federal level in Congress. Kaiser Permanente strongly supports state and federal efforts to make pharmaceutical manufacturers account for their prices, something that is already required of nearly all other participants in the health care marketplace.

We encourage HHS to consider any administrative steps that will hold the pharmaceutical industry more accountable to the public and policymakers when prices are set at unreasonably high levels and are increased at will. Any discounts, rebates, or other concessions achieved by plans must be negotiated based on starting price levels that would be unacceptable in any functioning market, and often result in unreasonably high final prices. As in any marketplace, however, disclosure of proprietary and confidential information could have a detrimental effect on competition. In efforts to increase transparency, HHS should be careful not to undermine payers' ability to negotiate on behalf of our members. The focus should instead be on shedding light on the advantageous conditions that pharmaceutical companies are able to exploit.

DTC Advertisements

Kaiser Permanente is very concerned about the effects of direct-to-consumer (DTC) advertisements for pharmaceutical products. The United States is one of only two countries that allows DTC advertising for pharmaceuticals. DTC advertisements contribute to overprescribing, increased demand for clinically inappropriate and more expensive versions of medications, and higher pharmaceutical spending that does not yield even marginal benefits. Based on our experience, commercial advertisements are not an appropriate venue for influencing complex treatment decisions. These decisions are best left to discussions between physicians and patients.

While Kaiser Permanente would prefer that HHS and Congress take broader steps to curtail DTC advertising by the pharmaceutical industry, we are generally supportive of policies that would require companies to conspicuously disclose the product's list price in the advertisement. Companies should be required to display the product's Wholesale Acquisition Cost (WAC) in all advertisements. Because pricing constantly changes, HHS should consider requiring display of the average per unit WAC price over a certain lookback period (e.g., the previous year) to make the program easier to administer and harder for companies to game. Pricing information should be displayed in a highly visible, conspicuous location on the advertisement. Making pricing information readily available to consumers will help educate the public about the high prices of pharmaceuticals and may put additional pressure on the industry to limit inappropriate advertising and pricing.

HHS should also take steps to prevent potential confusion at the point of service that could result from this policy change. We believe this could be accomplished through use of disclaimers encouraging consultation with physicians before making any treatment decisions and cautioning that the price displayed is the list price and patients may encounter different prices at the point of service based on their coverage.

Rebates & Pharmacy Benefit Managers

Kaiser Permanente appreciates the opportunity to provide feedback to HHS about rebates and pharmacy benefit managers (PBMs). Our unique, fully integrated delivery system requires a different approach to drug purchasing and price concessions than most health plans and PBMs. Kaiser Permanente generally purchases from and negotiates directly with wholesalers and pharmaceutical companies instead of outsourcing these functions. Our physicians and pharmacists work closely together to design and implement our formulary, and manage utilization for our members.

As part of the formulary management process, Kaiser Permanente prefers to negotiate discounts on prices upfront, but also negotiates for retrospective rebates when necessary. Discounts and rebates enable us to provide our members with affordable cost sharing and premium pricing. We manage our formularies, using applicable discounts and rebates, to favor benefit designs that yield better patient management and health outcomes and lower overall net drug costs.

Because of our ability to obtain discounts and rebates for drugs we purchase for use in Kaiser Permanente pharmacies, the long-standing safe harbor for discounts under the Anti-Kickback Statute is still very important to our business model and our ability to deliver high quality, affordable health care. Any alteration to the safe harbor that does not create a level playing field with the pharmaceutical industry could be detrimental to our ability to offer affordable benefit designs that promote optimal health outcomes. Upending current rules for price concessions and discounts could also impose considerable administrative and operational burdens on health plans, depending on how such a policy is implemented. Because changing the safe harbor would cause a very significant shift in current business practices, a well-intended policy could inadvertently increase costs for Medicare beneficiaries and other patients. We urge HHS to closely consult stakeholders throughout the policy development process to ensure the effects of any change are fully explored and that no unintended consequences are incurred.

D. Reducing Out-of-Pocket Costs

Kaiser Permanente shares HHS' goal of trying to provide patients with useful cost-related information and the lowest possible out-of-pocket costs. We offer the following response to your requests related to pharmacy gag clauses, increasing patient access to information about lower-cost alternatives, discount cards and coupons, and tradeoff considerations for health plans between premiums and cost-sharing.

Helping Patients Make Informed Decisions

Kaiser Permanente supports efforts to make more information about prices and costs available to patients. This could help physicians, pharmacists, and patients consider affordability when they discuss treatment options. The challenge, however, will be how to present the information in a useful and understandable way.

Elimination of Gag Clauses

As an employer of pharmacists, Kaiser Permanente strongly supports eliminating any use of so-called "gag clauses" that prevent pharmacists from informing patients about lower-cost, clinically comparable options or when it would be less expensive to pay for drugs out-of-pocket. Kaiser Permanente does not use gag clauses or impose other communication barriers between pharmacists and our members. While we believe that prohibiting gag clauses in the context of health plans and PBMs is appropriate, we urge

caution in imposing proactive requirements on pharmacists' communications at the point of sale. Depending on how they are structured, such requirements could impose significant administrative and operational burdens. Proposals should take this into account, but most importantly, patients should be able to receive full, unbiased information about their options at the point of sale.

Sharing Cost Information with Patients

Kaiser Permanente supports making information about lower-cost alternatives and drug price increases available to Medicare enrollees and other patients in a user-friendly format; the challenge is how to present this information in a useful and accurate way. The Blueprint suggests adding lower-cost alternative and drug price information to Part D's Explanation of Benefits (EOB), which is already a complex and lengthy document. Adding more information may make EOBs more difficult to read and understand. Drug prices also constantly change without warning—sometimes as often as every two weeks—so maintaining accurate pricing data will involve continuous updating. Thus, the EOB is not the appropriate vehicle for current information.

HHS also suggests that e-prescribing (eRx) systems could be further leveraged to inform prescribers and pharmacists about formulary options, expected cost-sharing, and lower-cost alternatives to share with patients during consultations. Existing systems already present formulary and some cost information, with certain limits:

- Most existing eRx applications include some degree of formulary checking and generic substitution suggestion. While useful, these functions are limited; existing eRx applications do not support active queries to determine the details of the specific patient's prescription drug coverage. The National Council for Prescription Drug Programs (NCPDP) is working on standardized messages and workflows to enable real-time benefit checking at the point of prescribing. Kaiser Permanente suggests that HHS encourage and facilitate this effort by NCPDP before moving forward with potential regulatory changes.
- Pharmacy systems²⁷ by necessity include the capability to determine the patient's specific drug benefits. Pharmacists already engage with patients to determine if there are options to reduce the patient's out-of-pocket expense.

Kaiser Permanente encourages HHS to work with health plans, providers, pharmacies, consumers, and other stakeholders to develop clear standards and a mechanism for patients to access meaningful and accurate information about costs, without imposing excessive administrative burdens on health plans, providers and pharmacies. The goal should be making sure that whatever is presented is clear to the patient. We look forward to working with HHS on a balanced solution that delivers useful information without over-burdening providers and the system.

Discount Cards & Coupons

While discount cards and coupons can provide short-term out-of-pocket cost savings to patients in some circumstances, they are effectively marketing tactics that enable inflated pricing and increased use of higher priced drugs, even when lower priced therapeutically equivalent drugs are available, to the detriment of all patients. Coupons and discount cards are currently prohibited in federally-funded health plans for sound policy reasons. We are concerned about any policy change that would increase use of coupons and discount cards, particularly when they steer patients toward expensive brand-name drugs where generics or lower priced multi-source drugs are available. Instead of offering coupons and discount cards, pharmaceutical companies should simply lower their prices.

²⁷ Systems that manage various pharmacy operations, such as prescription processing, inventory, signature capture, point-of sale, reporting, etc.

Regardless of whether a promotional discount is used, health plans bear the majority of costs for drugs dispensed to their enrollees. By pushing patients toward more expensive drugs when effective alternatives are available at a lower price, pharmaceutical companies increase health plans' drug spend, which in turn increases premiums for all consumers. According to some estimates, almost half of all drugs that are eligible for coupons and discount cards have a lower-cost generic competitor.²⁸ Another study found that coupons and discount cards increase prescriptions filled with brand-name formulations by more than 60 percent.²⁹ These promotional efforts also interfere with doctor-patient treatment decisions.

Equally important, pharmaceutical companies often design coupon and discount card programs with intent to work around formularies, decreasing plans' ability to negotiate discounts. When such strategies are deployed effectively, pharmaceutical companies need only make negligible price concessions to stay on formulary while still driving sufficient patient utilization through promotional programs. Coupons and discount cards are profitable marketing strategies. One study found that coupons for only 23 drugs increased domestic drug spending by between \$700 million and \$2.7 billion from 2007 to 2010.³⁰ This evidence strongly suggests that expanding the applicability of discount cards and coupons would undermine the Blueprint's goal to lower drug prices by creating a more level playing field in negotiations between pharmaceutical companies and drug purchasers.

Application of Rebates at Point of Sale³¹

Kaiser Permanente strongly agrees that high drug prices unfairly burden patients. Reforms that correct market dysfunction and limit the pharmaceutical industry's ability to price arbitrarily are necessary to achieve meaningful reductions in prices over the long-term. These types of reforms are likely to be more effective and sustainable than changes to health plan benefit structure, which could raise overall premiums and would do nothing to lower underlying prices.

While requiring application of rebates and price concessions at the point of sale (POS) may provide limited relief to some patients, it would also increase Medicare Part D plan premiums for all beneficiaries. These policies would also be very difficult to administer, which could in turn raise costs even further. For example, rebates often depend on performance (volume, market share, growth, etc.) measured *after* dispensing. Drug prices are also unpredictable and fluid, increasing or decreasing during the plan year, and causing rebates to change as well. Even use of an estimate introduces a subjective and complex adjustment that will add to the cost of administering Part D benefits, which could be passed on to Part D enrollees, contrary to CMS' intent to keep Part D plans affordable.

It is also important to consider that individual enrollee cost-sharing at POS will vary depending on whether the drug is subject to copayments or cost-sharing. Member copay amounts often do not change with fluctuating drug price, thus limiting the affordability benefits patients would experience at POS. All enrollees, however, see the benefits of price concessions in the form of lower plan premiums.

Kaiser Permanente agrees that the issue of rebates and price concessions, and how they should benefit Part D enrollees, deserve attention. But much more work needs to be done by stakeholders and CMS before large policy changes can be adopted.

²⁸Van Nuys, K. et al. (2018) *A Perspective on Prescription Drug Copayment Coupons*, Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California, available at:

http://healthpolicy.usc.edu/documents/2018.02_Prescription%20Copay%20Coupons%20White%20Paper_Final.pdf

²⁹Dafny, L. et al. (2016) Undermining Value-Based Purchasing—Lessons from the Pharmaceutical Industry, *New England Journal of Medicine* 375:2013-2015, available at: <https://www.nejm.org/doi/full/10.1056/NEJMp1607378>

³⁰ *Id.*

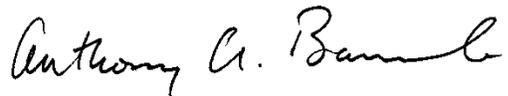
³¹ For additional Kaiser Permanente comments on this issue, please refer to our comments on the *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program* (CMS-4182-P).

Kaiser Permanente Comments
HHS Blueprint to Lower Drug Prices & Reduce Out-of-Pocket Costs

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Kaiser Permanente appreciates the opportunity to provide feedback in response to the RFI. We again applaud HHS's important contribution to the national conversation around the need to reduce high drug prices. We would be pleased to discuss these comments and our own pharmacy and drug purchasing experience within our integrated delivery system. Please contact Anthony Barrueta at 510.271.6835 or anthony.barrueta@kp.org; Laird Burnett at 202.216.1900 or laird.burnett@kp.org; or Polly Webster at 202.216.1900 or polly.f.webster@kp.org.

Sincerely,

A handwritten signature in black ink that reads "Anthony A. Barrueta". The signature is written in a cursive, flowing style.

Anthony A. Barrueta
Senior Vice President, Government Relations