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July 16, 2018

The Honorable Alex Azar  
Secretary  
Department of Health and Human Services  
200 Independence Ave., SW  
Washington, DC 20201  
Submitted electronically via regulations.gov

Dear Secretary Azar:

AARP is pleased to submit the following comments on the Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (83 Federal Register 22692.). AARP, with its nearly 38 million members in all 50 States, the District of Columbia, and the U.S. territories, is a nonpartisan, nonprofit, nationwide organization that empowers people to choose how they live as they age, strengthens communities, and fights for the issues that matter most to families such as healthcare, employment and income security, retirement planning, affordable utilities and protection from financial abuse.

The rising cost of prescription drugs is a key priority for Americans, especially for older Americans. Those age 65 and older use prescription drugs more than any other segment of the U.S. population, often on a chronic basis. However, older Americans continue to struggle to afford the drugs they need, and the prices of prescription drugs continue to rise. In 2015, the average price of brand-name drugs widely used by older Americans increased by 15.5 percent<sup>1</sup> and, per unit, Part D drugs costs rose nearly 6 times faster than inflation from 2011 to 2015.<sup>2</sup> AARP continues to support reforms that will lower drug prices and provide relief to older Americans struggling to afford needed medications.

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<sup>1</sup> S. Schondelmeyer, L. Purvis, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2015*, (AARP PPI, 2016) available at <https://www.aarp.org/content/dam/aarp/ppi/2016-12/trends-in-retail-prices-dec-2016.pdf>.

<sup>2</sup> U.S. Department of Health & Human Services (HHS) Office of Inspector General, OEI-03-15-00080, *Increases in Reimbursement for Brand-name drugs In Part D* (2018) <https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf>.

AARP shares HHS' goal of reducing prescription drug prices and costs while ensuring beneficiary access to appropriate medications. Older Americans' health and financial well-being are increasingly affected by high and growing drug prices, and we appreciate HHS's ongoing efforts to find new ways to address this challenge. AARP strongly believes that it is critical that any proposals to lower prescription drug costs don't simply shift the costs around in the health care system without addressing the root problem: the prices set by pharmaceutical companies. As we outline below, while we are supportive of some of the concepts and proposals put forth by HHS, we are concerned that the Blueprint does not go far enough in proposing reforms that will effectively get at the root of this problem and substantially lower drug prices.

We look forward to working with you to successfully implement policies that appropriately balance prescription drug affordability and access with the need for ongoing innovation.

### **AARP supports efforts to prevent manufacturers from using REMS to delay or block competition**

FDA can require drug manufacturers to develop a Risk Evaluation and Mitigation Strategy (REMS) to help ensure that patients can gain access to potentially beneficial drugs, while limiting risks that drugs with serious safety concerns are not used improperly. REMS restrictions on the distribution of a drug are often applied to a drug or drug class at the time of FDA approval and are meant to ensure that the use of potentially harmful drugs is confined to only those parties that can ensure that the drugs will not be misused.

Unfortunately, as noted in the Blueprint, some brand name drug companies are inappropriately utilizing REMS to prevent generic drug companies from accessing brand name drugs, which are needed for testing required for FDA approval. Such behavior slows or blocks generic competition that would place downward pressure on drug prices.

We recognize and applaud the steps that FDA has already taken to ensure that the REMS system is not abused in a way that impedes access to safe and effective generic drugs. However, these actions have not gone far enough to improve the availability of reference samples for generic drug companies to use in their development of low-cost generics. Consequently, AARP welcomes further actions by the FDA to thwart anti-competitive abuses of REMS by brand drug makers.

**CREATES Act:** AARP also supports the passage of the bipartisan Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (S.974/ H.R.2212), legislation which would address several of those key areas. The CREATES Act would combat certain anticompetitive practices used by some brand-name pharmaceutical companies to block market entry of lower-cost generic drugs.

The Congressional Budget Office (CBO) estimated that similar legislation would save taxpayers more than \$3 billion over the decade.<sup>3</sup> In light of the large cost-saving potential as well as the potential to improve access to life-saving treatments by increasing the availability of less expensive generic versions, we urge you to support Congress in moving this legislation forward.

### **AARP Recommends that HHS Continue to Speed the Availability of Interchangeable Biosimilars**

AARP strongly supports the creation of a workable biosimilar approval pathway that will provide consumers with access to safe, effective, and less expensive biosimilar products. Biologic drugs are used to treat many of the diseases that impact older populations. Unfortunately, the prices of such treatments can put them out of reach for many consumers, even those with comprehensive health insurance.

AARP appreciates and strongly supports the goal of ensuring that interchangeable biologic drugs are safe and effective. However, AARP also firmly believes that FDA must ensure that it does not elevate the burden of proof for interchangeability to a degree that it becomes unattainable. This designation is incredibly important, as it will allow pharmacists to substitute a biosimilar for the reference product without the involvement of the prescriber. This will help encourage adoption of biosimilars and enhance savings and access, much like what happens with traditional generic drugs.

Notably, FDA already evaluates biosimilarity and comparability whenever brand name biologic manufacturers change their manufacturing processes. These changes result in brand name biologic drugs that are considered highly similar—not identical—to the originally approved product, and are treated as interchangeable in the U.S. market with little or no clinical testing.<sup>4</sup> Given FDA's long record of safely performing such evaluations, it seems evident that the burden of proof for biosimilar-to-reference product interchangeability should not be any greater than what is currently required to demonstrate interchangeability following a manufacturing change.

AARP also believes that it is extremely important that FDA retain the flexibility to modernize its approach to evaluating whether a biosimilar product can be designated as interchangeable with a reference product. Establishing a standard that relies heavily on clinical studies could prevent FDA from benefitting from future advances in non-clinical analytic techniques.

Finally, AARP strongly supports increased efforts to educate patients and prescribers about the value, safety, and efficacy of biosimilar and interchangeable biologic drugs,

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<sup>3</sup> CBO scored the Fair Access for Safe and Timely Generics Act (H.R. 2051) that would require brand-name manufacturers to sell samples to potential generic manufacturers. These savings occur due to availability of lower-priced generic drugs for individuals enrolled in Medicare and Medicaid. Total savings would be larger if CBO took into account the availability of lower-priced generic drugs for people with private health insurance.

<sup>4</sup> M. McCamish, J. Pakulski, C. Sattler, and G. Woollett, "Toward Interchangeable Biologics," *Clinical Pharmacology & Therapeutics*, Vol 97(3): 215-217.

which will help increase acceptance and utilization of these less expensive products as they become available.

**Shortening the market exclusivity period for brand name biologics:** While not specifically noted in the Blueprint, AARP has consistently stressed that the 12-year market exclusivity period granted to brand name biologic drugs is too long. An unnecessarily lengthy market exclusivity period will impede access to biosimilars, reduce competition, and increase costs for consumers, employers, and taxpayer-funded programs like Medicare and Medicaid. Given that a growing proportion of the drug development pipeline is comprised of expensive biologic drugs, AARP strongly urges that FDA and HHS monitor the development of the biosimilar market and, if necessary, support efforts to reduce or eliminate the excessive exclusivity periods for biologic drugs.

### **AARP Supports Increased Drug Pricing Transparency**

In the Blueprint, HHS describes its plan to pursue improved drug pricing transparency. AARP agrees that price information will be a critical component to making prescription drugs more affordable for consumers and taxpayers. We also strongly support greater transparency for consumers and health care providers at the point of prescribing and the point of sale.

However, AARP is mindful that transparency can have negative repercussions if not appropriately directed. For example, the Federal Trade Commission (FTC) has repeatedly found that price competition may suffer if pharmacy benefit managers (PBMs) are required to disclose specific negotiation terms or rebate amounts. Thus, we strongly urge HHS and FDA to ensure an appropriate balance between the desire for more information and the possibility of competitive harm.

**Medicare and Medicaid Dashboards:** AARP applauds HHS' efforts to make Medicare and Medicaid drug prices more transparent by updating its pricing dashboards and strongly urges the Department to continue updating these valuable resources on a regular basis. We particularly appreciate the new data on manufacturer rebates and recommend that HHS continue to add more comprehensive information on rebates in the future.

**Research and Development Costs:** AARP strongly supports more transparency in the prescription drug development and pricing process, particularly in cases of drug manufacturers that benefit from taxpayer-funded research. Since the pharmaceutical industry routinely cites research and development (R&D) costs (rather than, for example, costly advertising) to explain their high prices, increased transparency could provide much needed clarity and a better understanding of the industry's pricing methods.

**Direct-To-Consumer Drug Price Disclosure:** HHS proposes having FDA evaluate the inclusion of list prices in direct-to consumer (DTC) advertising. AARP believes that

providing this information will help make patients and prescribers more aware of prescription drug prices. However, given that the effects of DTC advertising are still subject to debate, we strongly encourage HHS to also consider studying the effects of DTC on consumer choice, cost, and clinical outcomes in order to determine whether the potential benefits of DTC advertising outweigh its potential harms. HHS should also consider implementing a moratorium on DTC advertising for new prescription drug products until manufacturers are able to provide clear and convincing evidence of safety and effectiveness within the broader population.

## **AARP Supports Continued Progress on Value-Based Purchasing Arrangements**

AARP shares HHS' goal of working to better align the price of a drug with the value that it provides to patients rather than pricing that reflects simply what the market will bear. While AARP broadly supports the concepts behind value-based purchasing arrangements, we recognize that value-based designs face challenges in their implementation.

For example, AARP is aware that there is currently no universal definition of value, nor is there consensus on the standards and data that should be used when evaluating the value of prescription drugs. Consequently, we strongly urge HHS to provide ample opportunity for public input before widely implementing value-based purchasing arrangements for pharmaceutical products.

AARP is also aware that it can be difficult to obtain the data needed to create value-based purchasing agreements. For example, desired outcomes like symptom control or improved quality of life are rarely included in claims data and cannot be used as a basis for outcomes-based agreements. Moreover, manufacturers, providers, and payers may not have the necessary data and infrastructure to track needed data, or be willing to share data with other entities in the supply chain. These challenges should be addressed prior to implementing value-based purchasing arrangements.

In addition, some value-based purchasing arrangements do not result in savings until after a prescription is filled or administered. Given that beneficiaries' out-of-pocket costs occur at the point of sale, these savings could be difficult to pass along to beneficiaries. HHS should also find ways to address this challenge.

AARP is also concerned by research indicating that there is little evidence that value-based purchasing results in lower spending or better quality for patients.<sup>5</sup> As such, we urge HHS to ensure that value-based purchasing tools are only implemented when there is strong clinical evidence to support their use.

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<sup>5</sup> E. Seeley and A. S. Kesselheim, "Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?" *The Commonwealth Fund* (2017) <https://www.commonwealthfund.org/publications/newsletter/2017/oct/outcomes-based-pharmaceutical-contracts-answer-high-us-drug>.

Finally, AARP is mindful that value-based purchasing agreements remain in their infancy and international experience indicates that meaningful savings could take years or decades to materialize.<sup>6</sup> Further, value-based purchasing agreements have thus far only involved a small subset of drugs. As such, this approach should not be expected to provide a meaningful reduction in drug prices in the near future.

**Consumer Safeguards:** AARP strongly believes that robust consumer safeguards must be included in efforts to pursue value-based purchasing arrangements for prescription drugs. More specifically, HHS should ensure that consumer access to necessary prescription drugs is not negatively affected. As part of these efforts, appeals processes should be evaluated and improved to help ensure that they are not too complicated or cumbersome for enrollees to successfully navigate. Appeals processes must be transparent, easy-to understand, and fair in order for them to function as a true recourse. HHS should also be willing to regularly revisit and make changes to these processes as necessary to ensure beneficiary access.

We also strongly recommend HHS include a transparent, comprehensive, and publicly available monitoring process as part of any value-based purchasing arrangements. As part of the monitoring process, AARP encourages HHS to identify formal processes for regularly engaging and involving consumers and their advocates, including techniques such as consumer experience surveys and focus groups.

**Best price policy:** AARP appreciates the Administration's concern that Medicaid's best price policy could reduce drug manufacturer interest in entering value-based purchasing agreements. However, we believe that these concerns are unfounded, particularly given HHS' willingness to assist manufacturers in developing value-based designs that do not violate best price requirements. In fact, CMS recently issued its first-ever approval of a state plan amendment proposal that will permit it to pursue CMS-authorized supplemental rebate agreements—which are exempt from the Medicaid best price rule—for use in value-based purchasing arrangements.<sup>7</sup>

AARP encourages HHS to continue assisting in the development of value-based purchasing agreements by answering questions concerning manufacturers' arrangements and providing future guidance that identifies best practices and lessons learned.<sup>8</sup> Finally, should HHS decide to revisit the best price requirement, AARP strongly believes that Medicaid must retain access to prescription drug prices that are equal to or better than what they current receive under current policy.

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<sup>6</sup> N. Bisserbe, "For new Trump Drug Plan, a Cautionary Tale in Italy," *Wall Street Journal*, April 17, 2018.

<sup>7</sup> Centers for Medicare and Medicaid Services, "**CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers**," **Press Release, June 27, 2018.**

<sup>8</sup> Centers for Medicare and Medicaid Services, Medicaid Drug Rebate Program Notice, Release No. 99, For Participating Drug Manufacturers, July 14, 2016, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-099.pdf>.

## **AARP Supports Improved Formulary Flexibility for Medicare Part D Plans**

HHS proposes changes to Medicare Part D that would increase formulary flexibility and help strengthen plans' ability to negotiate with drug companies. Broadly speaking, AARP supports the use of well-designed drug formularies that help protect Medicare beneficiaries from high prescription drug prices, improve access, and encourage the utilization of high-value medicines. However, any changes to Medicare Part D formulary rules must be accompanied by improvements to its exceptions and appeals processes to ensure that they function as a true recourse for enrollees.

AARP urges caution in changing requirements that Part D plans must cover all or substantially all drugs within the six protected categories and classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants). The protected classes policy was developed to prevent risk segmentation and help ensure beneficiary access to certain types of drugs. However, AARP recognizes that changing the protected classes could potentially improve plan sponsors' ability to negotiate prices with drug manufacturers. As such, AARP supports HHS periodically reviewing, re-evaluating, and potentially modifying some or all of Part D's six protected classes of drugs. In exploring this option, we strongly encourage HHS to take precautions to ensure this change would not negatively affect enrollee access to necessary prescription drugs.

AARP recommends that any changes to formulary requirements be accompanied by extensive improvements to the exceptions and appeals processes under the Part D program. In its 2017 report, the Medicare Payment Advisory Commission (MedPAC) found that Part D's exceptions and appeals process can be time consuming, frustrating and burdensome for some individuals.<sup>9</sup> Exceptions and appeals processes must be transparent, easy to understand, and fair in order for them to function as a true recourse. HHS should also be willing to regularly revisit and make changes to these processes as necessary to ensure beneficiary access

As with any significant program change, changes to Medicare Part D coverage should be accompanied by extensive education and outreach to help beneficiaries and providers understand the new rules and their options, as well as the continued importance of carefully evaluating their plan options each year. Therefore, we strongly urge HHS to monitor plan sponsors' use of prior authorization or step therapy for drugs that were in the protected classes to help ensure that such techniques are only used when clinically appropriate. Moreover, we strongly urge that plans be required to provide clear and understandable information to beneficiaries explaining why prior authorization or step therapy is required for a specific medication.

Finally, AARP continues to encourage CMS to undertake broad efforts to educate beneficiaries and other stakeholders on the Part D exceptions and appeals process. CMS' data show that a significant share of audited Part D plans have difficulties in this

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<sup>9</sup> MedPAC, *March 2017 Report to Congress, Medicare Payment Policy*, [http://www.medpac.gov/docs/default-source/reports/mar17\\_medpac\\_ch14.pdf](http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf)

area. For example, many give enrollees too little information about the rationale for a coverage denial or fail to demonstrate that they have reached out to prescribers for additional information to make a coverage decision.<sup>10</sup>

### **Lowering Out-of-Pocket Costs for Beneficiaries with High Drug Costs**

**Out-of-Pocket Limit:** AARP encourages HHS to pursue policies that could help limit out-of-pocket spending under Medicare Part D. While Part D beneficiaries are only responsible for 5 percent of their prescription drug costs after they enter catastrophic coverage, this can still result in prohibitively high out-of-pocket costs for beneficiaries taking expensive drugs.<sup>11</sup> Data has shown that the number of enrollees who reach the catastrophic coverage limit has been rising since 2010, growing at an annual rate of 9 percent between 2010 and 2015, compared with 1 percent annually before 2010. Gross spending above the catastrophic (i.e., out-of-pocket) threshold also grew more rapidly during that period, rising at an annual 26.6 percent, compared with an annual 12 percent before 2010.<sup>12</sup> Meanwhile, the median annual income for people with Medicare is slightly more than \$26,000 and one in four beneficiaries have less than \$15,250 in savings.<sup>13</sup>

AARP also strongly believes that efforts to restrain Part D enrollees' out-of-pocket costs must be appropriately offset with policies that do not negatively affect the sustainability of the Medicare program. Moreover, any efforts to reduce out-of-pocket costs must be coupled with efforts to address the underlying problem – the prices set by drug manufacturers.

### **Exclusion of manufacturer discount from True Out-of-Pocket (TrOOP) costs:**

AARP opposes efforts to reduce or exclude the manufacturer discount on brand name or biosimilar drugs that is provided to beneficiaries in the Part D doughnut hole from the TrOOP. Every year, nearly 11 million Medicare beneficiaries fall into the doughnut hole, while only about 3 million exit it and reach catastrophic coverage.<sup>14</sup> Once those beneficiaries reach catastrophic coverage, their cost-sharing requirement is reduced to 5%, a significant drop from the cost-sharing required from the time they meet their deductible until they reach catastrophic coverage. AARP is concerned that reducing or excluding the manufacturer discount from the TrOOP would keep beneficiaries in the doughnut hole for significantly longer, thereby significantly increasing the amount they are required to pay out-of-pocket for needed medications.

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<sup>10</sup> Ibid.

<sup>11</sup> Juliette Cubanski, Tricia Neuman, Kendal Orgera, and Anthony Damico, "No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending," Issue Brief, Kaiser Family Foundation, November 2017.

<sup>13</sup> Gretchen Jacobson, Shannon Griffin, Tricia Neuman, and Karen Smith, "Income and Assets of Medicare Beneficiaries, 2016-2035," Issue Brief, Kaiser Family Foundation, April 2017.

<sup>14</sup> [http://www.medpac.gov/docs/default-source/reports/mar17\\_medpac\\_ch14.pdf](http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf)

## **AARP Recommends that HHS Undertake Analysis of Potential Impact of Shifting Reimbursement of Certain Drugs from Medicare Part B to Part D**

AARP is acutely aware that Medicare spending on Part B drugs has grown substantially in recent years, particularly on many high-cost specialty products. Part B prescription drug spending more than doubled from \$11 billion to \$26 billion between 2007 and 2015. Further, beneficiary cost sharing is 20 percent with no out-of-pocket limit, leaving some older adults and people with disabilities with out-of-pocket costs that can reach as much as \$100,000 per year<sup>15</sup> or more. Like all Americans, Medicare beneficiaries cannot continue to absorb the costs associated with skyrocketing prescription drug prices indefinitely.

Moreover, unlike Medicare Part D, prescription drugs covered by Part B are not subject to practices used by pharmacy benefit managers and Part D plans to help contain costs, such as formularies, utilization management, or price negotiation. Instead, providers are directly reimbursed for the drugs they administer at the average sales price of the drug plus 6 percent. There is a concern that this reimbursement methodology incentivizes providers to use higher-cost drugs.

While we appreciate the impetus behind the proposal to shift prescription drug coverage from Medicare Part B to Medicare Part D, we strongly urge HHS to also consider whether to address prescription drug costs directly in the Part B program, as well as undertake a thorough analysis to better understand how this proposal would work, including the impact on beneficiaries, plans, and the federal government. More specifically, we urge HHS to consider:

- *Shifting drugs from Part B to Part D should not increase beneficiary cost-sharing or raise premiums.* Most beneficiaries have supplemental insurance that covers some or all of their cost-sharing for the drugs they receive under Part B. Such coverage is not available for Medicare Part D. Thus, for beneficiaries with supplemental coverage, shifting Part B drugs to Part D would likely cause their cost sharing to rise considerably. Further, Medicare Part D cost sharing is often considerably higher than Medicare Part B cost sharing: a recent analysis of 2016 drug costs estimated that average out-of-pocket costs were about 33 percent higher for Part D-covered new cancer therapies than for those covered in Part B.<sup>16</sup> HHS should be mindful of the potential for increased cost sharing that could affect access and affordability, as well as the possibility that shifting coverage of expensive drugs to Part D could increase premiums to the point that they become prohibitively expensive.
- *Shifting drugs from Part B to Part D should include plan for Medicare beneficiaries who are not enrolled in Part D.* Any plan to shift coverage of

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<sup>15</sup> Government Accountability Office, *Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly to Beneficiaries*, October 2015.

<sup>16</sup> M. Brow, R. Kane, *Avalere Analysis highlights Complexities of Transitioning Medicare Part B Drugs into Part D*, Avalere (2018) <http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d>.

products from Part B to Part D must ensure continued access to necessary drugs for the 14 million Medicare beneficiaries who are not enrolled in a Part D plan.<sup>17</sup>

- *Improvements to Part D exceptions and appeals processes are necessary.* Shifting drugs from Part B to Part D must be accompanied by improvements in the Part D exceptions and appeals processes. As described above, the Medicare Part D exceptions and appeals processes should be transparent, easy-to-understand, and fair in order for it to function as a true recourse for enrollees.
- *AARP strongly opposes any policy that would require beneficiaries to “brown bag” physician-administered drugs.* The practice of “brown bagging” drugs is when beneficiaries are required to purchase their physician-administered drugs at a pharmacy and bring them to their physician’s office to be administered. This practice is complicated, raises safety concerns, and is likely to be a barrier to treatment. Drugs requiring refrigeration could be spoiled, and drugs could be lost or otherwise damaged in transit. Many high-cost specialty drugs are valued at thousands of dollars per prescription, and beneficiaries would have little recourse if they lost a drug or stored it improperly.
- *Part D specialty tier thresholds should be updated before more formulary flexibility is applied to Part B drugs.* We encourage HHS to revise and update the monthly costs threshold for drugs placed on specialty tiers annually. The cost threshold for specialty drugs remained at \$600 for plan years 2000 through 2016. That threshold was increased by a small amount for 2017 (to \$670) and has again remained the same through the 2019 plan year. Given the rapidly increasing costs associated with prescription drugs, continuing to keep this cost threshold static could result in more and more drugs placed on the specialty tier with high cost sharing.

### **Point of Sale Rebates Could Lead to Unintended Consequences and Higher Premiums**

AARP has provided CMS with feedback in response to its request for comments on applying manufacturer rebates and pharmacy price concessions to the price of a Part D drug at the point of sale.<sup>18</sup> AARP shares CMS’ goal of reducing out-of-pocket prescription drug costs for Medicare beneficiaries, especially for those who require high cost drugs for chronic illnesses. In addition, we support efforts to increase transparency and accountability in the drug supply chain. However, we remain concerned that requiring manufacturer rebates and price concessions to be passed through at the point of sale could have unintended consequences and could lead to higher premiums for many beneficiaries.

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<sup>17</sup> MedPAC, *March 2017 Report to Congress*.

<sup>18</sup> January 16, 2018 Letter to Seema Verma, Administrator, Centers for Medicare & Medicaid services, from David Certner, Legislative Counsel and Legislative Policy Director of AARP providing comments on the Proposed Rule for the CY 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, Medicare Prescription Drug Benefits and PACE programs, <https://www.aarp.org/content/dam/aarp/politics/advocacy/2018/01/part-c-and-d-comment-letter-010818.pdf>

Currently, many Part D plans sponsors opt to use part or all of the rebates they receive from manufacturers to keep the premiums associated with their Part D plans stable and at reasonably low levels.<sup>19</sup> AARP is concerned that requiring rebates to be passed through at the point of sale would remove this option and, as CMS already acknowledges, lead to higher premiums for most beneficiaries.

In addition, it is unclear how many beneficiaries would see their out-of-pocket costs substantially decrease if rebates were required to be passed to the beneficiary at the point of sale, as many of the drugs included in protected classes rarely see sizable rebates.

AARP believes that any efforts to improve Medicare Part D should make such coverage more – not less – affordable for Part D enrollees. Consequently, we strongly urge CMS to conduct a comprehensive analysis to better understand the impact this change would have on out-of-pocket costs and Part D plan premiums before moving forward with any proposal to reconfigure existing rebate policies.

Moreover, AARP is concerned that requiring rebates and price concessions to be passed along at the point of sale could increase Medicare spending by disincentivizing manufacturers from providing higher rebates on brand-name drugs included in the Medicare Part D Coverage Gap Discount Program. In fact, CMS' analysis estimates that manufacturer rebates would be reduced over ten years by approximately \$10 billion to \$29 billion from point of sale rebates and by \$5 billion from point of sale pharmacy price concessions. Moreover, a recent CBO estimate concluded that implementing this policy would cost taxpayers \$43.4 billion over ten years.<sup>20</sup>

### **Better Pricing Information for Consumers**

AARP strongly supports efforts to ensure that Medicare beneficiaries are provided with information about cost sharing and the availability of lower cost alternatives. This information would be most useful at the point of prescribing, allowing the patient and their prescriber to make an informed decision regarding their treatment options. This type of information could also be expanded to include utilization management, such as prior authorization, which could help reduce the amount of resources devoted to responding to such coverage restrictions.

AARP also shares HHS concerns about the use of so-called gag clauses by Part D plan sponsors. These gag clauses can prohibit pharmacies from informing a consumer that a drug may be available for a lower cost if they choose to purchase it without using their insurance coverage. We appreciate CMS efforts in recent months to discourage plan sponsors from including these clauses in their contracts. AARP also supports legislation, S. 2553, the Know the Lowest Price Act, and S. 2554, the Patient Right to Know Drug Prices Act, that would permanently ban the use of gag clauses in Part D

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<sup>19</sup> <https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf>.

<sup>20</sup> <https://www.cbo.gov/system/files/115th-congress-2017-2018/dataandtechnicalinformation/53906-medicare.pdf>

plans, Medicare Advantage plans, plans sold on the Affordable Care Act (ACA) Marketplaces and plans covered by the Employee Retirement Income Security Act (ERISA). We urge you to support Congress in moving these two bills forward.

### **International Drug Prices**

In the Blueprint, HHS indicates that it is updating analyses to examine whether drug prices paid in other countries are driving some of the cost problems in the U.S. HHS suggests that it will explore increasing prices in other countries to offset high U.S. prices. While we encourage additional research and examination, we believe that a better focus of interest might be why other countries' prices are lower and how the US might replicate or benefit from their practices.

Further, even if the US forced other countries to pay higher prescription drug prices, there is no evidence that the increased revenue would lead to lower prices in the U.S. For example, a recent examination of drug company behavior after a tax windfall found that none of the 10 largest U.S. pharmaceutical companies indicated having plans to reduce prices, while half of them had already announced stock buybacks totaling \$45 billion.<sup>21</sup>

### **Long-term Financing Models Are Not a Solution to High Drug Prices**

The Blueprint inquires about establishing long-term financing models for the purchase of prescription drugs. While AARP understands the impetus behind such proposals, AARP believes that they effectively encourage exorbitant and unsustainable drug prices. Further, AARP is concerned that such new financing tools could introduce new inequities in access to health care based on income or health status. Would lenders of life-saving drug mortgages only provide loans to credit-worthy individuals? Could people at risk of dying before paying off such loans be denied one?

Operationalizing long-term financing approaches will also be complex. For example, program administrators would have to determine how to handle situations where a patient takes a drug for a meaningful period of time only to find out during the course of treatment that the drug has not been effective. There is also a danger that long-term financing could lead to even higher prices. For example, as more people find extremely expensive drugs to be "affordable," manufacturers could view it as an opportunity to charge even more for their products.<sup>22</sup> Finally, and perhaps most importantly, this type of funding mechanism should only be considered after drug manufacturers have adequately demonstrated that the price of their product is justified.

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<sup>21</sup>A. Slavitt, "Drug companies get tax windfall, but they're not reducing prescription prices," April 11, 2018, *USA Today*, <https://www.usatoday.com/story/opinion/2018/04/11/drug-companies-arent-using-tax-windfall-cut-prescription-prices-column/499230002/>.

<sup>22</sup> M. Andrews, "Buying costly drugs on the installment plan: Could it work?" *Health Shots; Health News from National Public Radio*, March 28, 2016, <https://www.npr.org/sections/health-shots/2016/03/28/472171503/buying-costly-drugs-on-the-installment-plan-could-it-work>.

## **AARP Has Strong Reservations about the Use of Copay Discount Cards and Coupons As they Do Not Lower Drug Costs**

HHS seeks feedback on the impact of manufacturer copay assistance and whether such assistance lowers consumer costs or drive increases in manufacturer list prices. AARP appreciates the need to lower out-of-pocket costs, but believes copay assistance issued by drug manufacturers is not the answer. Copay assistance does not address the fundamental problem with the high cost of prescription drugs – manufacturers’ prices—and allows drug companies to raise prices indefinitely without reducing demand. These higher costs will increase plan spending and ultimately plan premiums.

Copay assistance has become increasingly common. In 2009, there were fewer than 100 brand-name drugs with coupon programs. In 2016, that number had grown to more than 750.<sup>23</sup> Research has found that the introduction of a coupon or copay card is associated with higher retail spending for the product by an amount that is up to 4.6 percent higher over a period of 5 years.<sup>24</sup> In addition, price increases over time for branded drugs with coupons were found to be significantly above those for branded drugs without coupons. During the period between 2009 and 2016, prices for branded drugs with coupons increased by between 12 and 13 percent per year, compared with 7 to 8 percent for branded drugs without coupons.

The assistance offered via coupon and copay cards is also typically time-limited. As a result, consumers are often left with considerably higher cost sharing after the coupons expire. However, by that time consumers have already been discouraged from seeking lower-cost alternatives or generic versions. This is particularly problematic given research findings that more than half of the drugs offered in connection with copay cards have a lower cost therapeutic alternative available.<sup>25</sup>

Should HHS decide to pursue this proposal, copay assistance should be prohibited for brand name drugs that have a have generic equivalent. Further, AARP strongly believes that any efforts to limit patients’ out-of-pocket costs for prescription drugs should be implemented in conjunction with policy changes that will help reduce prescription drug prices.

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<sup>23</sup> Johnson, C.Y., “Secret rebates, coupons and exclusions: how the battle over high drug prices is really being fought,” *Washington Post*, May 12, 2016, [https://www.washingtonpost.com/news/wonk/wp/2016/05/12/the-drug-price-arms-race-that-leaves-patients-caught-in-the-middle/?utm\\_term=.4a0036baa022](https://www.washingtonpost.com/news/wonk/wp/2016/05/12/the-drug-price-arms-race-that-leaves-patients-caught-in-the-middle/?utm_term=.4a0036baa022).

<sup>24</sup>K. Van Nuys, G. Joyce, R. Ribero, D. Goldman, *A Perspective on Prescription Drug Copayment Coupons*, U.S.C. Schaeffer Center for Health Policy & Economics (2018) [http://healthpolicy.usc.edu/documents/2018.02\\_Prescription%20Copay%20Coupons%20White%20Paper\\_Final.pdf](http://healthpolicy.usc.edu/documents/2018.02_Prescription%20Copay%20Coupons%20White%20Paper_Final.pdf).

<sup>25</sup> J.S. Ross, A.S. Kesselheim, “Prescription-Drug Coupons – No Such Thing as a Free Lunch,” *New England Journal of Medicine*, September 26, 2013, <https://www.nejm.org/doi/pdf/10.1056/nejmp1301993>.

## **Additional Ideas to Lower Drug Prices**

While not included in the Blueprint, AARP believes there are additional policies that will help to lower prices and reduce costs for beneficiaries and public insurance programs.

**Price Negotiation:** Unlike private insurance plans, Medicare cannot negotiate prescription drug prices with pharmaceutical companies. AARP supports enabling the HHS Secretary to use the bargaining power of Medicare's 55 million beneficiaries to negotiate for lower prescription drug prices.

**Prohibit Anticompetitive Pay-for-Delay Agreements:** AARP supports prohibiting patent settlement agreements between brand name and generic drug manufacturers that delay the availability of less-expensive generic drugs, costing the US billions of dollars.

**Importation:** AARP believes that we should reduce barriers to global price competition by allowing for the safe importation of lower priced but equally effective drugs. Previously, HHS has utilized this authority when experiencing a drug shortage.

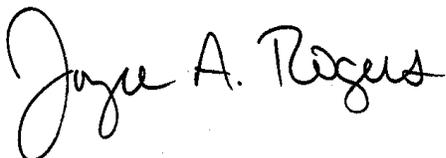
**Part D Rebates:** AARP supports requiring drug manufacturers to provide Medicaid drug rebates for prescription drug dispensed to low-income Part D enrollees. This change could save \$145 billion over ten years, according to the CBO.<sup>26</sup>

## **Conclusion**

In closing, AARP continues to believe that additional administrative and legislative reforms are needed in order to reduce drug costs for beneficiaries and for our public insurance programs. Such reforms could include allowing the Secretary of HHS to have more ability to negotiate drug prices for the Medicare program, allowing for the safe importation of lower cost prescription drugs from other countries, and curtailing anti-competitive behaviors that deter generic entry into the market.

Again, AARP appreciates the continued focus on high drug prices and we look forward to working collaboratively with HHS to address the critical problem of unsustainable growth in prescription drug prices.

Sincerely,



Joyce A. Rogers  
Senior Vice President  
Government Affairs

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<sup>26</sup> CBO, *Options for Reducing the Deficit: 2017 to 2026*, December 2016.