



Matthew Eyles
President and CEO

July 16, 2018

The Honorable Alex Azar
U.S. Department of Health and Human Services (HHS)
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: FR Doc. 2018–10435: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (“Blueprint”)

Dear Secretary Azar:

America’s Health Insurance Plans (AHIP) appreciates the opportunity to comment on the provisions of the HHS Blueprint and for soliciting feedback through the Request for Information (RFI) published in the Federal Register on May 16, 2018. AHIP commends the Administration for its thoughtful and comprehensive focus on out-of-control prescription drug prices. We support the goals of lowering prescription drug prices and reducing out-of-pocket costs for patients and consumers.

AHIP is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

Insurance Providers Unequivocally Support Lower List Prices for Prescription Drugs. AHIP and our members commend the Administration’s acknowledgement in the Blueprint and subsequent statements that high list prices for drugs set and controlled solely by manufacturers are a major problem across the American health care system. However, since the Administration’s release of the Blueprint, a narrative has emerged that some entities in the system may be imposing barriers to lower list drug prices from manufacturers and/or have incentives to maintain high list prices. For the record, **AHIP and our member companies support lower list prices for drugs that result in lower net prices and costs for consumers and payers and stand ready to work with any drug manufacturer who seeks to voluntarily lower their list price.**

AHIP’s members negotiate lower costs for patients and consumers, working with health care providers and drug companies to provide access to high-quality treatments and services at the most competitive prices. Health insurance providers offer comprehensive coverage for prescription drugs delivered through retail, specialty, and mail order pharmacies. Health plans also provide coverage for physician-administered drugs, biologics, and devices in outpatient and inpatient settings. Consequently, health plans have a unique perspective into the pharmaceutical supply chain and a 360-degree view of the workings of the broader U.S. health care system.

Rising drug prices are an urgent national problem. AHIP appreciates that the RFI includes many promising strategies and policy approaches to lower costs for consumers. Consistently and

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persistently rising drug prices place a heavy burden on all Americans – especially for patients who rely on them, and taxpayers who fund public programs such as Medicare and Medicaid. We fully support the HHS goals of reducing drug prices and lowering patient out-of-pocket costs. We stand ready to work with HHS and Congress to advance market-oriented solutions that address the root of the problem of soaring prices for prescription medicines.¹

Recently-Announced Price Increases Demonstrate Manufacturers Control Drug Prices. In recent weeks, numerous drug manufacturers announced significant price increases across hundreds of different pharmaceutical products.² During June and the first two days of July alone, drug companies announced over 100 separate price increases for prescription drugs with an average increase of 31.5 percent and median percentage increase of 9.4 percent.³ These mid-year, across-the-board price increases for drugs, including extremely expensive treatments for cancer and blood disorders, far exceed recent inflation rates and present access and affordability challenges for all Americans. While one manufacturer has now announced it will delay the changes, this latest round of price increases is part of a pattern that clearly and unambiguously proves the root cause of the pharmaceutical cost crisis: high drug prices and price increases are driven entirely by drug manufacturers.

Other research findings clearly demonstrate the size and scope of the affordability problem created by pharmaceutical manufacturers. For example:

- A May 2018 AHIP analysis concluded that 23.2 cents out of every premium dollar goes to pay for prescription drugs—making this the largest component of health care spending—with prescription drug spending outpacing the amount spent on physician services, office and clinic visits, or hospital stays.⁴ This is a conservative estimate because it excludes drugs used in hospital inpatient settings.
- Launch prices for new treatments and specialty drugs can be staggering. According to the National Cancer Institute, most cancer drugs launched between 2009 and 2014 were priced at more than \$100,000 per patient per year, with more recent drugs featuring prices that exceed \$400,000.⁵
- Many drug companies increase these prices year over year, even multiple times a year, sometimes for decades. One study shows that the price of insulin has increased by more than

¹ AHIP Statement for the Record Submitted to the Senate Finance Committee “Prescription Drug Affordability and Innovation: Addressing Challenges in Today’s Market” June 26, 2018

<https://www.ahip.org/wp-content/uploads/2018/06/ahip-statement-for-sfc-rx-hearing-06-26-18.pdf>

² *Drugmakers defy Trump’s call to drop prices.* Politico. July 3, 2018.

<https://www.politico.com/story/2018/07/03/drugmakers-trump-drug-prices-668260>

³ See footnote 2.

⁴ *Where Does Your Health Care Dollar Go?*, AHIP, May 22, 2018. <https://www.ahip.org/health-care-dollar/>

⁵ National Cancer Institute—President’s Cancer Panel: Promoting Value, Affordability and Innovation in Cancer Drug Treatment. March 2018 <https://www.cancer.gov/news-events/cancer-currents-blog/2018/presidents-cancer-panel-drug-prices>

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240 percent over the past decade. The price of Lantus increased from \$88.20 per vial in 2007 to \$307.20 per vial in late 2017, while the price of Levemir increased from \$90.30 per vial to \$322.80 per vial during the same time period.⁶

- A June 2018 report from the HHS Office of Inspector General (OIG) found that unit costs for brand-name drugs in the Medicare Part D program rose nearly six times faster than inflation from 2011 to 2015. The average Part D unit cost increased 29 percent over this time frame. Six drugs had unit cost increases of more than 4,000 percent and four other drugs had unit cost increases exceeding 2,000 percent.⁷
- An independent analysis by a prominent consulting firm estimates that prescription drug spending for employer-sponsored plans will increase by 10.3 percent in 2018, with a 17.7 percent cost increase in specialty drugs and biologics. These spending increases are driven by rising prices rather than by increased utilization. This estimate was done before the latest round of manufacturer-announced price increases.⁸

The lack of competition, transparency, and accountability in the prescription drug market has created extended, price-dictating monopolies with economic power unrivaled in the U.S. economy. While this problem primarily relates to brand name drugs, certain generic drugs with limited or no competition also exhibit similar behaviors and impacts. Moreover, the problem may get worse given the drugs in the pipeline that will also enjoy protection from competition and likely carry extraordinarily expensive price tags.⁹ The simple truth is that everyone except for drug companies pays more.

KEY AREAS OF SUPPORT

We strongly support several legislative and regulatory steps that have the potential for providing consumers relief from high prescription drug costs through lower drug prices. We urge HHS to focus on market-based solutions that deliver real competition, remove barriers to full and fair negotiation, create more consumer choice, and ensure open and honest drug prices. Only these approaches will give consumers access to affordable medications, while also protecting and supporting innovations to deliver new treatments and cures for patients.

We therefore recommend implementing the following policies from the Blueprint that offer significant promise for putting downward pressure on prescription drug prices.

⁶ *Several Probes Target Insulin Drug Pricing*, Kaiser Health News, October 28, 2017. <https://www.nbcnews.com/health/health-news/several-probes-target-insulin-drug-pricing-n815141>

⁷ *Increases in Reimbursement for Brand-Name Drugs in Part D*, Department of Health and Human Services' Office of Inspector General (OIG), June 2018. <https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf>

⁸ *High Rx Cost Trends Projected to Be Lower for 2018*, Segal Consulting, Fall 2017

⁹ "A new wave of gene therapies ready to hit US shores" June 12, 2017 <https://www.biopharmadive.com/news/new-wave-gene-therapy-us-market-pipeline/444360/>

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Promoting Generic Competition. HHS should prevent brand-name drug manufacturers from using risk evaluation and mitigation strategies (REMS) to block competition from generic drug makers.

- The Food and Drug Administration (FDA) recently issued two draft guidance documents addressing this priority. To build on these efforts, we encourage HHS to take additional action to curb REMS abuses, such as requiring brand name drug manufacturers to assure availability of adequate samples for generic manufacturers by making it a condition of approval.
- We also support legislative efforts to grant FDA the authority to address egregious drug company practices such as product hopping, evergreening, REMS abuses, and “pay-for-delay” settlements that bar or delay generic drug availability.

Creating a Robust and Competitive Marketplace for Biosimilars. HHS should improve the availability, competitiveness, and adoption of biosimilars as affordable alternatives to expensive branded biologics. We appreciate that these efforts will include steps to educate clinicians, patients, and payors about biosimilar products to increase awareness about these treatments.

We also recommend that HHS further promote a competitive biosimilars marketplace by:

- Releasing the Biosimilar Innovation Plan to facilitate approval and adoption of biosimilars;
- Improving the efficiency of the biosimilar product development and approval processes;
- Finalizing guidance related to the interchangeability of biosimilars; and
- Reversing the previous administration’s policy on biosimilar product naming.

Enhancing Benefit Flexibility. HHS should allow Medicare Part D plans to address price increases for a sole source generic drug through changes to their formulary or benefit design during the coverage year. This flexibility would allow plan sponsors to quickly respond to price increases imposed by the only manufacturer of a generic drug.

Expanding Private-Sector Negotiation Tools. HHS should provide Medicare Part D plans with “full flexibility” in using formulary management tools for high-cost drugs for which rebates are often limited or unavailable (e.g., protected class drugs and drugs with no therapeutic competition). These tools, which are widely used in the commercial sector but currently limited in Medicare Part D would allow plan sponsors to have the leverage needed to negotiate better drug prices for Medicare beneficiaries.

For example, we support allowing protected class drugs with recent large price increases to be subject to additional formulary and utilization management tools.

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- The attached Milliman report¹⁰ found that among 124 protected class brand drugs, only 16 drugs had rebates. The Milliman report also found that, in an analysis of drugs with rebates by level of and type of market competition, protected class drugs had the lowest average rebates as a percentage of gross cost.
- AHIP believes that enhancing negotiation tools for the 108 protected class brand drugs with no rebates, which account for \$16.3 billion in Part D spending, suggest an opportunity for significant savings.

We also support leveraging negotiation techniques for Medicare Part B-covered physician administered drugs. As demonstrated in Part D, combining market-based tools with negotiating flexibility represents a superior approach compared to government-administered pricing.

Increasing Transparency. We commend the release of the enhanced CMS Drug Pricing Dashboards for Medicare Part B, Medicare Part D, and Medicaid. We believe the updated dashboards will help provide consumers with additional information to make informed decisions, showcase price hikes by drug companies, highlight drugs that have not increased in price, and recognize when competition is working.

We also support requiring the disclosure of list prices in direct-to-consumer ads and other appropriate mediums. We believe such a disclosure could help mitigate anticompetitive pricing practices.

Updating Star Rating Methodology. HHS should update the methodology used to calculate Drug Plan Customer Service Star Ratings for Medicare Part D plans, especially when appropriately managing the utilization of high-cost drugs. This would be an important step toward ensuring that Star Rating measures are aligned with the goal of reducing unnecessary use of high-cost drugs.

KEY AREAS OF CONCERN

While we strongly support many ideas and potential solutions in the RFI, as highlighted above, we have some concerns with several ideas and proposals. In some cases, we believe the proposals are based on incorrect assumptions; are not supported by data; and would create higher prices and/or more complexity in the drug pricing and distribution system. For those items, we offer the following perspectives.

¹⁰ AHIP commissioned Milliman actuaries to study prescription drug rebates in the Part D market, in particular (1) prevalence of drugs with rebates; (2) rebate levels as a percentage of gross cost by level and type of market competition; and (3) cost and cost trends for drugs with and without rebates. The attached report provides the results of Milliman's analysis. Note that throughout the report and AHIP's comments, rebate refers only to manufacturer rebates and excludes pharmacy rebates. Gross drug cost refers to the cost of a drug at point-of-sale, prior to the impact of any post-point-of-sale price concessions such as manufacturer or pharmacy rebates. Finally, note that rebate percentage refers to rebates as a percentage of gross drug cost.

Plans Strongly Support Lower List Prices and Lower Net Costs for Consumers. Health insurance providers aggressively negotiate, either directly or through a contracted pharmacy benefit manager (PBM), with drug companies for lower costs for consumers, employers, government agencies, and other customers. Health plans pass savings directly to these parties in the form of both lower out-of-pocket costs and reduced premiums. However, the RFI appears to suggest that health insurance providers may instead favor drugs with high list prices and high rebates at the expense of lower costs.

Simply, health insurers have no such interest in higher prices.

- Health insurance providers operate in a competitive environment, attracting new customers through plans that deliver compelling value. They are strongly incentivized to negotiate low costs to offer more robust benefits and/or lower premiums and thereby attract more customers and enrollees. A plan's success in lowering costs can determine its market share, competitiveness, and overall success.
- AHIP members unequivocally support policies that would lower drug prices versus current levels. We also support policies to limit price increases and thereby reduce costs for consumers and other stakeholders. Given the history of inflated list prices and price increases, including for products on the market well past their original market exclusivity period, and other questionable marketing and legal practices, we are highly skeptical that they will voluntarily change their industry culture and other business practices in a way that would lower prices in a true and sustained way.¹¹ Assessments of the drug pipeline suggests prices will be an even bigger problem in the future.¹²
- Notwithstanding, if lower net costs ultimately can be achieved through lower list prices, AHIP would welcome a reduction in rebates. However, in the absence of substantially lower list prices for all pharmaceutical products, it is critical that payers continue to have access to all necessary market-based tools to reduce drug prices and costs such as negotiations for rebate payments.

Negotiated Discounts are Primarily a Function of Competition – Except when Policies Limit the Leverage Plans Have to Negotiate Discounts. As stated in the RFI, HHS has previously suggested that increasing the percentage of costs imposed on plans in the catastrophic phase would incentivize plans to negotiate more concessions from manufacturers and lower costs for high-priced drugs. AHIP strongly disagrees with the basic premise of this proposal – that incentives alone will produce such cost reductions. Instead, plans obtain deep discounts in exchange for preferred formulary placement and lower patient cost-sharing that result in greater market share for drugmakers' products, but only if plans can leverage competition between manufacturers.

¹¹ "Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher." January 6, 2018. <https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html>

¹² Gene Therapy: Pipeline of Possibilities but Challenges for Pricing, January 25, 2018. <https://www.lexology.com/library/detail.aspx?g=7f317d05-abbb-4919-b601-001b4cbc106d>

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In fact, plans are already fully incentivized to negotiate vigorously for lower costs as their business model requires attractive benefit offerings that convince consumers to enroll, which is only possible if the plan negotiates lower drug costs. On the other hand, drug companies are incentivized to provide price concessions only when leverage exists.

Competition is essential for negotiating significant rebates. Where no competitive market dynamic exists for specific drugs, plans lack leverage to demand and obtain substantial rebates. Manufacturers are empowered to set and increase list prices, often at extraordinary levels, with few repercussions. The reality is deceptively simple – drug companies set high prices and increase them because they can.

- The Milliman report found that among drugs with rebates, percentage rebates were higher on average for drugs with more direct competition. For example, among Part D brand drugs with rebates, drugs with direct brand competition had average rebates of 39 percent and drugs with three or more generic manufacturers had average rebates of 34 percent. AHIP believes the difference is apparent when contrasted to drugs with less competition: protected class drugs (14 percent), drugs without direct brand competition or a generic substitute (23 percent), and drugs with one or two direct generic manufacturers (27 percent).

However, a lack of leverage prevents negotiation of significant discounts. Plans can negotiate larger rebates only when they have leverage to do so (i.e., preferential treatment of competing products), clearly showing that negotiation is driven by leverage, rather than by incentives alone. Therefore, changes in the Part D benefit that reduce government subsidies but do not increase competition and plan leverage would therefore do nothing but increase costs for consumers.

- The Milliman report shows that 87 percent of protected class brand drugs (108 of 124 protected class drugs) did not have any rebates. Those 16 drugs that had rebates averaged at a 14 percent level.
- AHIP believes the data show that even if competition exists, the lack of leverage caused by the policies around protected class drugs drastically reduces the ability of plans to negotiate savings.

High List Prices and List Price Increases Create the Need for Rebates – Not the Other Way Around. The RFI suggests that high rebates may cause high list prices and price increases. AHIP strongly disagrees. We believe that rebates neither contribute to high list prices set by drug companies nor prevent them from lowering list prices. Also, there are no assurances that lower rebates would lead to lower list prices. Rather, the challenge of high drug prices has been documented for decades and came well before rebates were prevalent.

The problem of high list prices is not new. Instead, setting high drug prices and increasing them is and has been **an intentional, persistent, and pervasive decades-long pharmaceutical strategy to**

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maximize profits. Reports from the 1970s^{13 14}, 1980s^{15 16}, 1990s^{17 18}, early 2000s¹⁹, and the most recent decade²⁰ make that clear.

¹³ *Drug Anti-Substitution Laws Attacked.* November 16, 1977, The Washington Post.

“A Senate subcommittee was told yesterday that so-called anti-substitution laws, which once were necessary to protect the public from inferior drugs, have degenerated into devices for keeping drug prices unnecessarily high.”

“Food and Commissioner Donald Kennedy said that there is virtually no difference between generic prescription drugs, such as tetracycline, and the more expensive brand name varieties, such as terrmycin or symycin, even though drug companies often sell the latter for as much as 300 to 700 per cent more.”

¹⁴ *Brand Name Drug Sales Defended.* November 17, 1977, The Washington Post.

“Subcommittee chairman Gaylor Nelson (D-Wis.) noted that the last five Food and Drug Administration commissioners have said [...] that drug companies spend four times more promoting drugs than researching and developing new ones.”

¹⁵ *Unfairly High Drug Prices Cheat The Sick And Elderly, Panel Told.* April 22, 1987, Miami Herald.

“Prescription drug manufacturers have unfairly increased prices and profits at the expense of the sick and elderly”

“Yet the subcommittee’s survey of 24 major drug manufacturers found that companies made \$4.7 billion on price increases while research and development expenditures rose only \$1.6 billion.”

¹⁶ *The troubling Cost of Drugs That Offer Hope.* February 9, 1988, New York Times.

“The Armour Pharmaceutical Company introduced [...] the first blood-clotting factor for hemophiliacs. [...] There was one catch: This high-tech drug costs five to eight times as much as older versions, bringing the cost of a year’s supply to more than \$25,000. That puts the drug out of the reach of many patients whom it is a matter of life and death.”

¹⁷ *The Costs Of Medicine; Drug Prices Are Hostage To Greedy Firms.* June 30, 1993, Dallas Morning News.

“The theory of a free-market economy is that when demand is high, sales go up and prices go down so that more people can afford to buy, which pushes sales even further up and prices even further down. But it doesn’t work that way with medicines.

On the contrary, a study by the U.S. General Accounting Office reveals that drug costs have increased at a much greater rate than inflation, far outstripping the overall rise in the consumer price index. Over a six-year period ending in 1991, the cost of some of the most commonly prescribed medications doubled and even quadrupled.”

¹⁸ *Seniors ‘Priced Out’ Of Needed Drugs.* November 4, 1999, St. Petersburg Times.

“Bristol Myers Squibb, Schering, Lilly and Pfizer all made about 20 percent profit in 1998 [...] while the prices of their drugs raced ahead of the inflation rate.”

¹⁹ *Drug Industry Saying Yes To Higher Prices.* February 2, 2008, The Wall Street Journal.

“GlaxoSmithKline PLC raised the price of antidepressant Wellbutrin XL by 44.5 percent from 2005 to 2007. Sanofi-Aventis SA raised the price of sleeping drug Ambien 70.1 percent. Shire PLC increased the price of its attention-deficit-disorder medication, Adderall XR, by 33.5 percent, while the price of cholesterol-fighting Lipitor – the world’s top-selling drug, which brought in roughly \$13 billion last year for Pfizer Inc. – rose 16 percent.”

²⁰ *America’s Drug Firms Need A Stiff Dose of Self-Restraint; Prescription Prices March Relentlessly Upward.* July 2, 2014, The News Tribune.

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The need for government action is also not new. Manufacturer pricing practices have led Congress to intervene on numerous occasions. For example:

- In 1984, Congress passed the bipartisan Hatch-Waxman Act, which paved the path for a robust generic market to create competition and reduce prices.²¹
- In 1992, Congress passed the Omnibus Budget Reconciliation Act of 1990, which in part created the Medicaid Drug Rebate Program and provided some relief to state budgets.²²
- In 2003, Congress passed the bipartisan Medicare Modernization Act, creating the Medicare prescription drug coverage program (Part D) to lower drug prices and costs for Medicare beneficiaries.²³
- In 2010, Congress passed the Biologics Price Competition and Innovation Act of 2009, to encourage savings through a robust biosimilar and an interchangeable market.²⁴

Rebates are a market-based response to high prices. Rebates do not cause high prices; drug companies set prices high and then increase them. Rebates are a market-based response to drug company practices of setting high prices and then increasing them and reflect plan efforts to negotiate

“A newly released AARP study has found that, in the first three months of 2004, drug companies jacked up the wholesale price of the prescriptions most used by older Americans by an average of triple the rate of inflation.”

²¹ Richard F, “The Ongoing Regulation of Generic Drugs,” *The New England Journal of Medicine*, November 15, 2007, 1993. https://www.researchgate.net/publication/5842975_The_Ongoing_Regulation_of_Generic_Drugs

“In 1984, only 18.6 percent of U.S. prescriptions were written for generic products. The Hatch–Waxman Act aimed to inject price competition into the prescription-drug market while honoring legitimate claims to intellectual property rights by brand-name drug manufacturers that invested large sums in research and development.”

²² Statement by Senator Pryor of Arkansas. Medicaid prescription drug pricing: hearing before the Subcommittee on Health for Families and the Uninsured of the Committee on Finance, United States Senate, One Hundred First Congress, second session, on S. 2605 and S. 3029, September 17, 1990.

https://archive.org/stream/medicaidprescrip00unit/medicaidprescrip00unit_djvu.txt

“Like all health care programs, State Medicaid programs are under tremendous financial pressure as a result of spiraling health care costs. In 1988, Medicaid paid \$3.3 billion for prescription drugs, and that was the third highest category within all Medicaid spending. That amount was more than the amount that was expended for physician care payments. Drug price inflation, rather than increased use, accounts for virtually all of the increased Medicaid drug expenditures. And looking ahead in 1990, which of course we are in the midst of but have not completed, Medicaid prescription drug costs are expected to total some \$4.4 billion for this year.”

²³ H. Rept. 108-391 - Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

<https://www.congress.gov/congressional-report/108th-congress/house-report/391/1?q=%7B%22search%22%3A%5B%22medicare+modernization+act+2003%22%5D%7D&r=84&overview=closed>

“While seniors are taking more drugs than any other demographic group, they are often paying the highest prices”

²⁴ CBO estimated that the federal government would save \$25 billion over 10 years due savings from lower prices gained by a robust biosimilar market. <https://www.cbo.gov/publication/24808>

more reasonable and lower drug costs. For example, in Part D, rebates have been effective in reducing costs for beneficiaries through low premiums²⁵ and will likely continue to lower costs for beneficiaries.²⁶ Absent dramatically different drug company pricing practices, removing or severely limiting rebates likely will increase costs and impair patients' access to affordable prescription drug coverage.

Rebates do not drive prices. Evidence shows that the percentage of rebated drugs is decreasing and that list prices are also consistently rising whether drugs are rebated or not.

- A recent HHS OIG report states: “Total reimbursement for all brand-name drugs in Part D increased 77 percent from 2011 to 2015, despite a 17-percent decrease in the number of prescriptions for these drugs [...] After accounting for manufacturer rebates, reimbursement for brand-name drugs in Part D still increased 62 percent from 2011 to 2015... In addition, the percentage of brand-name drugs for which manufacturers paid rebates decreased [over this period].”²⁷
- The Milliman report found no clear correlation between percentage rebate levels and average price trends among brand drugs with rebates. However, the Milliman report shows that among drugs with rebates, the drugs with higher average annual cost per beneficiary had lower average percent rebates.
 - For example, the Milliman report shows that among Part D brand drugs with rebates, non-specialty/non-protected class drugs had a lower average annual cost per beneficiary (\$1,367) when compared to the average annual cost of specialty drugs (\$8,476) and protected class drugs (\$4,200). However, the Milliman report shows the opposite relationship for rebates. Among drugs with rebates, non-specialty/non-protected class drug average rebate percentage (35 percent) was higher than average rebate percentage for specialty drugs (24 percent) and protected class drugs (14 percent).

Rebate Proposals Distract from the Fundamental Threat of High Drug Prices. Proposals aimed at rebates divert attention from the true reason for high drug costs: drug manufacturers' ability to demand and command unreasonably high prices by taking advantage of a broken market. Many of the highest priced drugs lack competition. Policies that promote moderate prices and encourage

²⁵ Table 14-5, Changes in average Part D premiums, 2007–2017, shows stable Part D premiums since the beginning of Medicare Part D Program. See page 408 at: http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf

²⁶ The 2018 Annual Report of the Medicare Trustees lowers the projection of Part D cost. The trustees noted that their projected increase in rebates “is a major reason for decreases in overall Part D costs when compared to the 2017 Trustees Report.” See page 143 at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf>

²⁷ Increases in Reimbursement for Brand-Name Drugs in Part D, Department of Health and Human Services' (HHS) Office of Inspector General (OIG), June 2018. <https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf>

increased utilization of cheaper alternatives, including generics, interchangeable biologics, and other biosimilars, are the only means of lowering drug costs.

List prices drive costs. Inflated list prices and price increases are what drive consumer costs, including copayments and premiums, and what drive costs for employers, governments, and other entities that pay for drugs.

- In fact, the Milliman report shows that the average annual cost per beneficiary for brand drugs with rebates was lower than for brand drugs without rebates. AHIP sees this as clear proof that the average annual cost per beneficiary for these drugs – which we understand effectively reflects list prices - is not driven by rebates.

Most drugs do not generate rebates, including the most expensive drugs. The vast majority of drugs dispensed have no rebates.

- For example, the Milliman report found that nearly 90 percent of Part D drug claims were for drugs with no rebates. The Milliman report also found that, when measured on an individual drug basis (i.e. not a script count basis), approximately 70 percent of brand drugs did not have significant rebates – 64 percent of brand drugs receive no rebates at all and 9 percent of drugs did not have significant rebates, where the percentage rebates were less than 12 percent.
- Further, physician-administered drugs, which account for 30 percent of prescription drug spending, typically do not receive rebates.²⁸
- Simply, the focus on rebates ultimately discourages solutions that would reduce the cost of expensive brand drugs that do not have rebates and fails to address the fundamental problem of high prices.

Potential Alternative to the Existing Rebate System in the RFI Raises Numerous Concerns.

AHIP appreciates HHS' desire to simplify the existing system, enhance transparency, and reduce list prices. The RFI suggests these goals could be achieved, in part, by eliminating or substantially reducing the use of rebates to reduce brand drug costs, potentially through changes to the anti-kickback safe harbor and instead by requiring a system that relies on "fixed" pricing negotiations between plans and manufacturers. Based on our limited understanding of the proposal from its description, we assume that HHS may be envisioning a system for brand drugs akin to the maximum allowable cost (MAC) system commonly used for generic drugs.

While plans negotiate price concessions with drug companies, plans generally do not take possession of prescription drug products directly from the manufacturer. Rather, drug products are purchased, stored, and dispensed to a plan's enrollee by the pharmacy, with a wholesaler typically facilitating the acquisition of drugs from the manufacturer. Upon dispensing a drug, plans reimburse the pharmacy at a negotiated rate.

²⁸ Trends in Specialty Drug Benefits, Pharmacy Benefit Management Institute, 2017.

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Since pharmacies must stock a wide array of prescription medicines to serve their communities and do not make formulary and coverage decisions for their customers, they do not move market share for branded drugs. Pharmacies are therefore unable to negotiate significant concessions to drug acquisition prices – unlike when purchasing generic drugs produced by multiple manufacturers. If our assumptions about fixed pricing are accurate, a structure without rebates would need to include an extensive and equally complex system of chargebacks akin to rebates so that manufacturers would reimburse pharmacies when the drugs they dispense have an acquisition cost greater than negotiated rates.

Though we strongly support HHS’ goals relating to simplification, transparency and list prices, we would like to share our serious concerns with this alternative approach.

Pharmacy financial risk. This system of chargebacks would pose significant and serious financial risks to pharmacies. For example, even if chargebacks were to work as intended, pharmacies could still experience cash flow problems between the time they buy and dispense extraordinarily expensive drugs and when they receive reconciliatory payments or credit from manufacturers. Also, it is likely that this cash flow issue would be exacerbated if the chargeback payments were to face regular or significant delay.

For example, assuming fixed price discounts were available, oral oncology drugs costing upwards of tens of thousands of dollars per month per prescription could pose crippling financial risks to pharmacies that acquired those products at their list price.

Complexity. This approach would require significant additional costs and create more complexities as the system would need to track and account for multiple “fixed prices” that would be negotiated by different payers for each drug. Moreover, despite these complexities, **there would be no actual assurances for lower net drug costs.**

Pricing. Severely restricting or eliminating rebates could increase transparency for up-front discounts negotiated by drug companies, **likely creating an even more anticompetitive pharmaceutical pricing environment and possibly increasing drug costs at a higher rate.**

- The Federal Trade Commission (FTC) and other economists have raised concerns about the anticompetitive effect of competitors knowing each other’s negotiated discounts for years. For example, The FTC has found that “whenever competitors know the actual prices charged by other firms, tacit collusion – and thus higher prices – may be more likely.”²⁹

²⁹ Letter from FTC to Assembly Member Greg Aghazarian, 7 September 2004.
https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf

- Congressional testimony indicates similar conclusions from antitrust authorities in other countries – that more transparent contracted prices tend to lead to higher prices.³⁰
- The Congressional Budget Office (CBO) has also noted that “the current secrecy of rebate negotiations makes it difficult for manufacturers to monitor one another’s behavior and thus impedes collusive activity: When rebates are confidential, manufacturers can pursue their self-interest in increasing their drug sales at the expense of their competition by offering rebates without fear for retaliation.”³¹

Value-based Arrangements. Limits on the use of rebates could inhibit efforts to encourage value-based arrangements, which typically require retroactive pricing adjustments based on the collection of data for and calculation of agreed-upon quality metrics. In addition to inhibiting value-based arrangements, preventing retroactive payments would severely limit a plan’s ability to incentivize better pharmacy performance through payment-based quality improvement programs.

Legal Issues. There are several legal considerations that must be worked out before HHS could move forward with a payment system without rebates.

If manufacturers were to sell drugs (either directly or through chargebacks) to pharmacies at different prices rather than pay rebates, it could raise significant questions under anti-trust laws such as the Robinson-Patman Act. Class action lawsuits under that Act in the 1990s, which challenged differential pricing practices, and settlements with multiple drug manufacturers that arose out of the litigation were a key reason for the rapid growth in and expanded use of rebates.³²

In addition, the noninterference clause, a critical feature of the Medicare Modernization Act of 2003 and Part D program, restricts government interference in private contracting and allows competitive market forces to deliver robust and affordable care for over 43 million Medicare beneficiaries.³³ Eliminating the use of rebate tools and requiring Part D plans to use only government-endorsed negotiation methods would clearly and substantially interfere with how plans, drug manufacturers,

³⁰ According to Paul Ginsburg, “the experience in Denmark, where the government, in a misguided attempt to foster more competition in a concentrated market, posted contracted prices in the ready-mix concrete industry[,] is instructive. Within six months of this policy change, prices increased by 15-20 percent, despite falling input prices.” <http://www.hschange.org/CONTENT/823/>

³¹ CBO, Letter to Joe Barton, Ranking Member, Committee on Energy and Commerce and Jim McCrery, Ranking Member, House Committee on Ways and Means, March 12, 2007. <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/03-12-drug%20rebates.pdf>

³² Pollak A. “Should the Exemption from the Robinson-Patman Act Apply to Pharmaceutical Purchases by Nonprofit HMOs?” <http://www.nyulawreview.org/sites/default/files/pdf/NYULawReview-73-3-Pollak.pdf>

³³ In 2003, CBO recommended against removal of the noninterference clause and estimated that “substantial savings will be obtained by the private plans and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree. Because they will be at substantial financial risk, private plans will have strong incentives to negotiate price discounts, both to control their own costs in providing the drug benefit and to attract enrollees with low premiums and cost-sharing requirements.” <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/fristletter.pdf>

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and pharmacies contract with each other. We believe protecting the noninterference clause is critical to ensure a robust private market and the sustainability of Medicare Part D.

Moreover, though the anti-kickback statutory exception for drug discounts would still remain after scaling back or eliminating anti-kickback safe harbor rules, such an act by HHS would likely create confusion, raise legal and financial risks, and substantially increase legal and financial costs for a range of stakeholders. This would also have a chilling effect on competitive negotiations between plans and manufacturers, leading to higher drug costs. Thus, rather than reduce administrative burdens and costs, a clearly stated goal of the Administration, it would instead significantly increase burdens and costs.

Transition Issues. If HHS addressed the aforementioned issues in a way that would not increase costs, then any limits on how rebates are structured, negotiated, or paid should only be taken as final steps after the building blocks of sustainable lower prices – meaningful competition and enhanced plan leverage – have been put into place. At that time, it would be critical for HHS to provide sufficient lead time so that health plans could evaluate the impact of potential regulatory (or legislative changes), undertake the process of negotiating and modifying contracts with pharmacies, manufacturers and other affected stakeholders, and obtain all necessary CMS guidance so plan actuaries could properly incorporate changes into prescription coverage benefits. Such lead times would need to account for the bidding cycle in Part D, under which Part D plan bids for the upcoming plan year (e.g., 2019) are required to be submitted by the first Monday in June of the prior year (e.g., 2018). The bids are a critical part of the competitive structure of Part D and are used to establish benefit packages, premiums, and government payments.

As noted, we applaud HHS efforts to consider ways to simplify and add transparency to the current drug distribution and payment system. But, as the Administration has acknowledged, the current system and related processes have evolved over time. They are the result of a gradual process where competitive market dynamics are continually molding the system. Government-driven efforts that attempts to centrally re-engineer the system, control competitive market dynamics, or do both will almost certainly have significant unintended consequences. We believe that HHS should instead focus its efforts on achievable regulatory steps that can enhance competition, improve negotiations, and hold drug companies accountable unless they provide lower net costs and lower prices.

AHIP Continues to Oppose Raising Beneficiary Premiums. To the extent HHS continues to consider the Part D point-of-sale (POS) RFI that CMS published in the *Federal Register* on November 28, 2017, AHIP reiterates the substantial concerns from our previous comment letter:

- Higher premiums for beneficiaries – the Administration itself estimated government and taxpayer costs would increase an estimated \$40 billion over 10 years,
- Ability of manufacturers to reverse engineer rebates negotiated by their competitors and thereby increase prices,
- Small and narrow distribution of benefit among beneficiaries,
- Promoting the use of more expensive branded products over their generic competitors, and

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- Running afoul of the non-interference clause.

Additionally, Low Income Subsidy (LIS) beneficiaries do not pay coinsurance and therefore would not receive meaningful benefit from this policy.

AHIP believes any proposal in this area must include comprehensive and transparent data analyses so that the impacts can be fully considered. To that end, AHIP is exploring potential research to further address these issues.

HHS Should Not Pursue New Levels of Government Interference in Private Contracting Arrangements. Many health insurance providers contract with PBMs to: negotiate with pharmacies over network participation and payment, negotiate with drug companies for discounts, and perform a range of other services involving administration of prescription drug benefits. AHIP has very serious concerns with suggestions in the RFI for imposing restrictions on the nature of contracting terms and conditions. These concerns include eliminating certain PBM compensations and imposing fiduciary obligations on PBMs.

- We believe such changes are unnecessary. As noted above, the incentives of health insurer are aligned with the goals of consumers and other stakeholders – to achieve low net drug costs so funds can be used for more robust benefits and lower monthly premiums. If a contracted PBM cannot deliver satisfactory results to its health plan partner, available options for the plan include the selection of an alternative PBM.
- In addition, government attempts to structure compensation arrangements that remove certain types of payments and/or impose new legal liabilities will ultimately increase rather than decrease administrative costs. They could also adversely affect how PBMs are able to negotiate with manufacturers on behalf of individual plan sponsors. These adverse impacts and higher costs would effectively be passed on to consumers and other purchasers through higher premiums, reduced benefits, or both.
- We are also concerned with the precedential impact of government imposing new restrictions on private sector compensation arrangements. Ultimately, health insurance providers are already accountable to their customers – consumers, employers, governments, and other payers – for the value of the benefits they offer. Rather than attempt to reengineer various processes within the drug distribution system, we recommend that HHS remain focused on obtaining better outcomes for patients. As the creators of Medicare Part D recognized the importance of protecting negotiations from government interference, we urge HHS to avoid a similar type of interference in these arrangements.

AHIP Supports Continued Savings Through a Medicaid Drug Rebate Program, Although Certain Changes Should be Considered. In general, under the Medicaid Drug Rebate Program, manufacturers of brand drugs are permitted to have their products covered by Medicaid only if they agree to pay minimum statutory rebates and supplemental rebates for price increases. Minimum rebates are also required for generic drugs. Manufacturers are also required to charge Medicaid programs no more than the “best price” available to other customers (generally in the commercial

market) if greater than the mandated discount. AHIP recommends that a number of changes be considered for the drug rebate program.

Best price. AHIP members believe that the best price component of the drug rebate program inhibits the ability of plans to obtain larger discounts for other payers and consumers. For example:

- A 1996 CBO report on best price, 6 years after the best price provisions of the Omnibus Budget Reconciliation Act of 1990 were first implemented, found that “in particular, the best-price provision has increased the prices paid by some purchasers in the private sector. Since Medicaid constitutes between 10 percent and 15 percent of the market for outpatient prescription drugs, pharmaceutical manufacturers are much less willing to give large private purchasers steep discounts off the wholesale price when they also have to give Medicaid access to the same low price. As a result, the largest discounts that pharmaceutical manufacturers give off the wholesale price - the best-price discounts - have fallen from an average of more than 36 percent in 1991 to 19 percent in 1994.”³⁴
- An April 2018 analysis found that the rebate share of branded drugs is roughly 31 percent for Medicare Part D, which is exempt from best price. By contrast, the report found the rebate share is only 16 percent for private insurers. While this report does not speculate on the potential impact of best price on the differential, we believe it plays a role.³⁵

Moreover, we believe the impact of best price on Medicaid programs is minimal as manufacturers are generally reluctant to offer steeper discounts because of best price, particularly given the higher statutory rebates included in the ACA.

We also are concerned about the adverse impact of best price on value-based arrangements. AHIP recognizes that best price is a statutory requirement, and therefore legislation would be needed to eliminate the requirement. In the meantime, however, we believe that HHS should consider using its regulatory authority to take certain steps to reduce the adverse impacts of best price on the commercial market. For example, HHS could issue guidance that clarifies and limits the reach of best price with respect to certain specified value-based arrangements between manufacturers and payers.

Minimum percentage rebates. AHIP notes the importance of the rebate percentage component of the Medicaid rebate program for state and federal government budgets, particularly with respect to high price drugs without competition that ordinarily do not generate rebates. For example, a 2018 Altarum Study found substantially higher rebates in Medicaid than Part D, likely resulting from the application of Medicaid-required rebates to drugs that do not otherwise generate significant rebates through negotiation.³⁶ We also note the importance of changes made by the Affordable Care Act (ACA) to extend rebates to drugs obtained by enrollees in Medicaid Managed Care plans. These

³⁴ How The Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry, January 1996. <https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/47xx/doc4750/1996doc20.pdf>

³⁵ The Impact of Prescription Drug Rebates on Health Plans and Consumers, April 2018. https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf

³⁶ See footnote 35

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plans cover a substantial and ever-increasing percentage of Medicaid enrollees. It is critical that the law continue to provide parity for states that use managed care plans to provide Medicaid benefits, whether currently or in the future.

However, we are also very concerned with the increasing impacts of high cost drugs on Medicaid.³⁷ We urge HHS and others to consider potential changes that might lower the overall cost of prescription drugs for state and federal payers in Medicaid. For example, studies show that states can optimize savings in Medicaid drug programs by using mechanisms to encourage the lowest-cost clinically effective drug products, rather than relying exclusively on the receipt of rebates. We recommend that HHS take steps to encourage states to use utilization management criteria and tools already being used effectively in some states, and commonly used outside of Medicaid.³⁸ We also believe HHS should strongly consider giving states and Medicaid health plans more flexibility (e.g., through demonstrations) to use restricted formularies and value-based arrangements, similar to flexibilities available for commercial health plans and Medicare Part D.

More broadly, as noted above, the key driver of high drug costs ultimately comes back to high prices set by manufacturers. Thus HHS must continue to focus on changes to enhance the competitive environment so that drug costs reflect vigorous competition and good faith negotiation.

ADDITIONAL AHIP RECOMMENDATIONS

In the attached chart, we provide numerous recommendations for HHS' consideration. Several are highlighted earlier in the letter. In light of continued manufacturer anticompetitive behavior, including continued price increases across most corners of the industry, our recommendations also include several bold steps that are available under existing law but are not addressed in the RFI, particularly for high-cost drugs that do not provide meaningful discounts.

28 U.S.C 1498. If a manufacturer fails to engage in reasonable, good-faith negotiations with payers, HHS could exercise its existing authority, codified at 28 U.S.C. section 1498, to introduce market competition that will better ensure negotiation takes place. The law allows the federal government to obtain generic versions of patented drugs from generic manufacturers, with the patent-holders receiving "reasonable and entire compensation" from the government for the patent use. Calls for

³⁷ According to a 2016 analysis by MACPAC, Medicaid drug claims that cost more than \$1,000 accounted for 0.6 percent of claims and 19.9 percent of Medicaid drug spending in 2011, which increased to 0.9 percent of claims and 32.4 percent of Medicaid drug spending in 2014. <https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf>

³⁸ For example, a 2015 study by the Menges Group <https://www.ahip.org/wp-content/uploads/2015/11/Medicaid-Pharmacy-Carve-In-Final-Paper-The-Menges-Group-April-2015.pdf> found that states using Medicaid managed care plans to encourage greater use of generics and lower-cost drugs had net prescription costs 14.6 percent lower than states "carving out" drugs from managed care. This translated into over \$2 billion net savings in state and federal expenditures in 2014.

See also: https://www.themengesgroup.com/upload_file/louisiana_carve_out_report_may_2018.pdf

HHS to invoke this law may have helped negotiations that lowered prices for ciprofloxacin in the wake of several anthrax attacks in 2001. While the provision technically applies only to federal programs, HHS could identify anticompetitive pricing practices and use this leverage to insist on lower list prices, which can benefit all consumers.³⁹

For example, the list price of Revlimid – a cancer drug marketed to treat multiple myeloma – has increased dramatically from \$6,195 for one month’s supply in 2006⁴⁰ to its current list price of a staggering \$69,547.81 for a 100-capsule bottle. This represents a 25 percent list price increase over the last 18 months alone and a several-fold increase from 2006. These pricing practices over the past decade has contributed to Revlimid becoming the second most expensive drug by aggregate costs in Medicare Part D, reaching \$2.7 billion in spending in 2016.

Independent Third-Party Assessor of Value. To develop an environment where true value-based purchasing can flourish, additional tangible actions beyond best price reform are necessary – the system must make concrete steps towards creating a commonly accepted definition of value that is both effective and practical for payers and consumers. Until such a definition can be developed, it will likely be difficult to make any significant progress towards an environment that promotes true value.⁴¹ Therefore, we recommend that HHS lead the industry by identifying and empowering a third-party entity (e.g., Institute for Clinical and Economic Review) that can objectively and fairly define and develop the concept of value.⁴²

In accordance with the shared goal of holding manufacturers accountable for outcomes, value should be defined to avoid manipulations by drug manufacturers that solely maximizes their revenue and profits. Instead, value-based purchasing agreements should work to protect payers and consumers by including significant up-front discounts, with incentive payments made only after sufficient time has passed to adequately assess whether pre-determined outcomes are met, and only on a graduated scale as long as the therapy continues to work.

Drug companies should have to provide to all payers the necessary amount of clinical, scientific, and outcomes-based data ahead of negotiations to ensure a level playing field and better align with true value.

Bolder Steps to Improve Benefit Flexibility in Part D. Additionally, we agree with the HHS proposal to allow Medicare Part D plan sponsors to use management tools and resources for protected class drugs that experience high list price growth. We recommend that HHS also consider exploring simplification of existing regulations that would provide more plan leverage to negotiate

³⁹ Brennan, et al. “A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health” 18 YALE J.L. & TECH. 275 (2016). https://www.yjolt.org/sites/default/files/kapczynski_18yjolt275_gk_0_0.pdf

⁴⁰ Kodjak, Alison. How a drugmaker gamed the system to keep generic competition away. NPR. May 17, 2018.

⁴¹ Kaltenboeck A., Bach P. “Value-Based Pricing for Drugs Theme and Variations” JAMA. 2018;319(21):2165-2166. <https://jamanetwork.com/journals/jama/fullarticle/2680422>

⁴² More Execs Expect Value-Based Reimbursement to Up Profitability, July 9, 2018. <https://revcycleintelligence.com/news/more-execs-expect-value-based-reimbursement-to-up-profitability>

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lower drug costs with drug companies and more flexibility to vigorously manage high priced drugs, including protected class drugs.

Some potential changes that HHS could explore include reduction in the number of protected classes, modifying the two-drugs-per-class requirement to one-drug-per-class, and utilization of preferred and non-preferred specialty tiers.

Alternatively, HHS could also explore the possibility of exercising exceptions for protected class drugs⁴³ in cases of extraordinarily high list prices, high list price increases, and a drug company's unwillingness to negotiate in good faith with Part D plan sponsors. Based on the Milliman analysis, AHIP believes that the protected class requirement strips plans of leverage to negotiate significant rebates and that HHS' current authority to exercise exceptions could lead to saving hundreds of millions of dollars every year. Moreover, protections could remain in place in Part D to ensure beneficiaries have affordable access (i.e., through the tiering exceptions process).

Necessary Transition Terms. Lastly, as discussed in detail above, we urge HHS to expand the ability for private payers to negotiate with manufacturers, rather than remove negotiating tools such as rebates. However, if HHS does choose to move forward with proposals involving rebates, we recommend that, in addition to ensuring adequate transition time, CMS consider testing such changes through voluntary demonstrations. This can minimize the potential for significant increases in administrative costs and system-wide complexity until the impacts can be assessed.

We look forward to providing any additional information you may need and to continuing to work together to improve the health of the beneficiaries our members serve.

Sincerely,



Matthew D. Eyles
President and CEO

⁴³ 42 USC 1395w-104(b)(3)(G)(i)(II)

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Improving Competition

Prevent Gaming of FDA Regulatory Process	
HHS Solicits Feedback on:	<i>Should HHS pursue policies that would improve competition and spur generic availability?</i>
AHIP Position:	SUPPORT HHS efforts to promote greater price competition by facilitating the availability and utilization of generic drugs.
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • AHIP commends HHS for including expedited and priority reviews for generic drugs where there is a lack of competition, recent guidance on REMS safety protocols, and listing brand-name drug companies that are withholding samples from generic drug manufacturers • We also support HHS policies and efforts taken to develop the FDA Drug Competition Plan and to facilitate greater generic drug availability and utilization, including the curbing of abuses of the REMS process by brand manufacturers. <ul style="list-style-type: none"> ○ To build on these efforts, we encourage HHS to take additional action to curb REMS abuses, such as requiring brand name drug manufacturers to assure availability of adequate samples for generic manufacturers by making it a condition of approval. ○ We also support legislative efforts to grant FDA the authority to address egregious drug company practices such as product hopping, evergreening, REMS abuses, and “pay-for-delay” settlements that bar or delay generic drug availability.

Promoting Innovation & Competition for Biologics	
HHS Solicits Feedback on:	<i>Should HHS pursue policies to improve the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics?</i>
AHIP Position:	SUPPORT HHS efforts to ensure a robust and competitive biosimilars market.
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • AHIP supports HHS policies around improving competition in the biologic market. <ul style="list-style-type: none"> ○ These policies represent important first steps to improve the availability, competitiveness, and adoption of biosimilars as an alternative to branded biologics. ○ For example, FDA should continue efforts to educate clinicians and patients about the safety and efficacy of biosimilars and efforts to address sample availability for biosimilar manufacturers. • We also recommend that HHS further promote a competitive biosimilars marketplace by: <ul style="list-style-type: none"> ○ Releasing the Biosimilar Innovation Plan to facilitate approval and adoption of biosimilars; ○ Improving the efficiency of the biosimilar product development and approval processes; ○ Finalizing guidance related to the interchangeability of biosimilars; and ○ Reversing the previous administration’s policy on biosimilar product naming. • AHIP also supports legislation that would require more robust FTC oversight of patent settlements between biologic and biosimilar manufacturers, shorten the exclusivity period for reference biologics to 7 years, and preserve the change made by the Bipartisan Budget Act of 2018 to extend the coverage gap discounts to biosimilars. • In addition, AHIP supports efforts to revisit state laws that may prevent uptake and utilization of biosimilars, such as anti-substitution laws that include burdensome notice requirements.

Negotiating Lower Drug Costs

Flexibility to Manage High Cost Drugs	
HHS Solicits Feedback on:	<p><i>Should Part D plan sponsors have flexibility to adjust formulary or benefit designs to address price increases for sole source generic drugs?</i></p> <p><i>Should Part D plan sponsors have full flexibility to manage high cost drugs that do not provide rebates or negotiated fixed prices, including protected class drugs?</i></p>
AHIP Position:	<p>SUPPORT providing Part D plans with additional plan flexibility to implement private market tools that could lower drug costs.</p> <p>SUPPORT providing Part D plans with tools to manage high cost drugs without rebates.</p>
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • AHIP continues to advocate for HHS to maximize plan leverage by reversing or relaxing certain Medicare Part D regulations that limit the extent to which plans can negotiate lower drug costs for beneficiaries, including: <ul style="list-style-type: none"> ○ Protected classes; ○ Two drugs per class/category; and ○ Preferred and non-preferred specialty drug tiers. • The protected class requirement strips plans of leverage to negotiate significant rebates. At the same time, it is unnecessary given protections in Part D to ensure beneficiaries have affordable access to drugs (i.e., tiering exceptions process). <ul style="list-style-type: none"> ○ The attached Milliman report¹ found that among 124 protected class brand drugs, only 16 drugs had rebates. The Milliman report also found that, in an analysis of drugs with rebates by level of and type of market competition, protected class drugs had the lowest average rebates as a percentage of gross cost (14 percent). ○ AHIP believes the data show that even if competition exists, the lack of leverage drastically reduces the ability of plans to negotiate any discounts. ○ Additionally, we believe that the 108 protected class brand drugs with no rebates, represents an opportunity for significant Medicare part D savings – these 108 drugs had gross costs of \$16.3 billion, suggesting hundreds of millions of dollars in unrealized savings per coverage year. • Therefore, AHIP supports HHS providing plans with more negotiating flexibility for Part D drugs that do not provide rebates, including for protected class drugs and drugs that are high priced and/or increase significantly in price over a given “look back” period. <ul style="list-style-type: none"> ○ We believe the statutory provisions at 1860D-4 of the Social Security Act give CMS substantial authority to add or remove drugs from protected class status.² ○ If CMS has the authority but chooses not to remove a drug class entirely from the protected class list, the agency should exercise the authority to exclude individual drugs within the class based on pricing practices. <ul style="list-style-type: none"> ▪ By allowing protected class drugs with recent large price increases to be subject to additional formulary and utilization management tools, HHS should provide plan sponsors with the leverage needed to negotiate better drug prices for Medicare beneficiaries.

¹ AHIP commissioned Milliman actuaries to study prescription drug rebates in the Part D market, in particular (1) prevalence of drugs with rebates; (2) rebate levels as a percentage of gross cost by level and type of market competition; and (3) cost and cost trends for drugs with and without rebates. The attached report provides the results of Milliman’s analysis. Note that throughout the report and AHIP’s comments, rebate refers only to manufacturer rebates and excludes pharmacy rebates. Gross drug cost refers to the cost of a drug at point-of-sale, prior to the impact of any post-point-of-sale price concessions such as manufacturer or pharmacy rebates. Finally, note that rebate percentage refers to rebates as a percentage of gross drug cost.

² 42 USC 1395w-104(b)(3)(G)(i)(II)

	<ul style="list-style-type: none">▪ In determining which drugs to cover by this change, HHS should make the look back period sufficiently long to capture price increases made over several years. HHS should also account for any substantial increase that occurs during any single year.▪ HHS should consider this approach for not only protected class drugs, but also for drugs that are required to meet the current CMS two drugs per class/category rule (in the event CMS does not remove that rule entirely). This would allow additional formulary and utilization management tools for those drugs.○ Even if the above changes are made, beneficiaries would retain the ability to obtain drugs through the exceptions process when clinically necessary.• HHS should also allow Medicare Part D plans to address price increases for a sole source generic drug through changes to their formulary or benefit design during the coverage year. This flexibility would allow plan sponsors to quickly respond to price increases imposed by the only manufacturer of a generic drug.• We also support leveraging negotiation techniques for Medicare Part B-covered physician administered drugs. As demonstrated in Part D, combining market-based tools with negotiating flexibility represents a superior approach compared to government-administered pricing.• AHIP also recommends that HHS explore the use of existing statutory authority, codified at 28 U.S.C. Section 1498, to encourage lower prices for high-cost drugs that do not provide meaningful discounts. This provision could introduce market competition for drugs protected by a patent if a manufacturer fails to engage in reasonable, good-faith negotiations with payers. The goal would be to provide incentives for real negotiation and discounts. Manufacturers that fail to negotiate would still receive “reasonable compensation” rather than their demanded prices.
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Drug Plan Customer Service Star Ratings

HHS Solicits Feedback on:	<i>Should the methodology used to calculate the Drug Plan Customer Service Star Ratings in Part D be updated to support better management of high-cost drugs?</i>
AHIP Position:	SUPPORT revising the Star Ratings program methodology to ensure that plans implementing effective management of high cost drugs are not adversely impacted.
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • AHIP understands HHS is referring to a measure in the Star Ratings system regarding the frequency of independent review entity reversals of coverage denials. • We agree that CMS should revise, through the notice and comment process, a change to the Star Ratings methodology that would eliminate potential disincentives to appropriate management of high cost drugs. • HHS should update the methodology used to calculate Drug Plan Customer Service Star Ratings for Medicare Part D plans, especially when appropriately managing the utilization of high-cost drugs and when implementing lock-in programs that limit an at-risk beneficiary’s access to opioids from negative impacts. • AHIP also recommends that the Star Ratings methodology be modified. • If the above changes are implemented, we also agree that CMS has existing means for oversight, audits, and enforcement activities to ensure plan compliance with all Part D program requirements. However, AHIP also believe CMS should explore ways to ensure more consistency and transparency in the independent review process, and would appreciate the opportunity to work with CMS on that issue.

Leveraging Negotiation for Part B Drugs

HHS Solicits Feedback on:	<i>Should private-sector negotiation be leveraged to lower Part B drug costs?</i>
AHIP Position:	SUPPORT HHS’ goal of negotiating lower Part B drug costs by using private-sector tools. However, we recommend a thoughtful and cautious approach moving forward.
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • The RFI suggests at least two potential ways to generate savings for Part B drugs – shifting Medicare coverage for all or some physician administered drugs to Medicare Part D; and utilizing competitive bidding and other negotiation tools within the Part B payment structure. • We support HHS’s intention as reflected in the RFI to identify particular drugs or classes of drugs in Part B where there are savings to be gained by moving them to Part D. • However, HHS should also carefully analyze: <ul style="list-style-type: none"> ○ Administrative costs and complexity of potentially moving Part B drugs that are not typically dispensed through retail pharmacies, particularly for stand-alone Part D plans; ○ Impact on beneficiary out of pocket costs; ○ Impact on Part D bids and premiums; and ○ Potential for using new special enrollment opportunities and waivers of late enrollment penalties to facilitate Part D enrollment for those who do not have alternative coverage for the affected drugs. • Though moving all Part B drugs to Part D would require legislation, the Administration should carefully and thoughtfully investigate the possibility of steps it could take in the meantime, including as an example a voluntary demonstration covering a narrow set of oral and inhalation Part B drugs typically dispensed from pharmacies. • We also support HHS expanding the use of available negotiating tools for physician-administered drugs within the Part B payment framework, such as competitive bidding and drug cost negotiations.

Expanding Consumer Transparency

Price Transparency for Medicare Beneficiaries & Medicaid Enrollees

HHS Solicits Feedback on:	<i>Should Part D plans provide beneficiaries with information on drug price increases? What other ways can price transparency be increased in Medicare, Medicaid, and other forms of health coverage?</i>
AHIP Position:	SUPPORT expanded disclosure of drug prices, price increases, and lower-cost alternatives to consumers.
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • AHIP commends actions already taken by HHS to hold drug makers accountable for their price increases by updating the CMS drug pricing dashboards for Medicare Part B, Medicare Part D, and Medicaid to help make overall prescription drug trends more transparent to the consumer. • While AHIP broadly supports expanded disclosure, we would have serious concerns and possible objections under the following circumstances: <ul style="list-style-type: none"> ○ Such requirements prove to be overly burdensome for plans to implement and administer. ○ The disclosure puts proprietary information at risk of exposure. • We also note there could be significant technologic, operational, and fiscal challenges in implementing such requirements. • Therefore, we urge HHS to work collaboratively with industry on these proposals.

Price Transparency in Direct-to-Consumer (DTC) Advertisements

HHS Solicits Feedback on:	<i>Should HHS require drug manufacturers to disclose list prices in DTC advertisements?</i>
AHIP Position:	SUPPORT requiring greater pricing transparency in direct-to-consumer advertisements.
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • AHIP supports the HHS goal of lowering drug list prices by requiring drug manufacturers to disclose list prices in DTC advertisements. We also support evaluating the impact of growing use of DTC advertisements and studying alternative, more effective ways for conveying clinical information to consumers. • In addition, other disclosure requirements could help further HHS’ goal to lower drug prices. <ul style="list-style-type: none"> ○ Drug manufacturers should be required to disclose pricing information, such as regarding intended launch price, cost of treatment, and research and development costs, during the approval process. ○ Further, drug manufacturers should be required to report price increases that exceed an established threshold and provide justification for why such increases were warranted. • FDA should also look at other mediums to deliver cost information to the consumer. <ul style="list-style-type: none"> ○ For example, HHS could facilitate the creation of more tools and resources that would allow providers to share accurate and real-time information to the consumer about cost, benefit structure, and potential treatment alternatives while the drug is being prescribed.

Pharmacy Gag Clauses

HHS Action:	<i>CMS has issued guidance prohibiting pharmacy gag clauses in Medicare Part D.</i>
AHIP Position:	SUPPORT Part D guidance CMS has already released on gag clauses, as we have supported similar legislative proposals.
Key Considerations & Recommendations:	<ul style="list-style-type: none">• AHIP agrees that consumers should be able to obtain prescription drugs at the lowest available price and pharmacists should not be constrained from informing consumers if there is a lower “cash” price.• While use of pharmacy gag clauses appears to be extremely limited and possibly non-existent, the anti-gag clause provision can still be an important protection in specific cases.• HHS should note that the purchasing of drugs outside health coverage can have certain adverse impacts. For example, it can inhibit the ability of plans to apply safety edits at point of sale, and to engage in disease management and care coordination efforts. Therefore, HHS statements on this issue should be carefully crafted to avoid encouraging cash purchases by enrollees with health coverage.

Drug Payment Arrangements

Value Based Arrangements	
HHS Solicits Feedback on:	<i>Should CMS develop demonstration projects to test innovative ways to encourage value-based care and lower drug prices, and should Part D plans be able to price or cover high-cost drugs differently based on their indication?</i>
AHIP Position:	<p>SUPPORT HHS efforts to encourage the healthcare system to better determine prices and encourage utilization based on value.</p> <p>HOWEVER, these efforts should recognize and incorporate elements that address the complexity of determining fair and appropriate arrangements for many drugs.</p>
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • AHIP supported a recent change in CMS policy that allows value-based designs in Medicare Advantage. However, that provision does not include value-based designs in Part D. We recommend that CMS modify its position so value-based designs in Part D are permitted. • We also support CMS in conducting demonstrations to hold manufacturers accountable for outcomes. However, HHS should consider several principles in guiding such demonstrations to prevent drug manufacturers from manipulating value into a mechanism that solely maximizes their revenue and profits. <ul style="list-style-type: none"> ○ The demonstrations should explore the potential benefits of an independent entity such as the Institute for Clinical and Economic Review (ICER) that would provide an objective assessment of value for drugs that exceed a certain price threshold. ○ The CMS Innovation Center should design demonstrations to include significant up-front discounts, with incentive payments made only after a sufficient amount of time has passed to adequately assess whether pre-determined outcomes are met, and only on a graduated scale as long as the therapy continues to work. ○ Manufacturers should have to provide all payers with the necessary amount of clinical, scientific, and outcomes-based data ahead of negotiations to ensure a level playing field and better align with true value. • It is critical to note that value-based arrangements ultimately are no substitute for changes in the competitive environment that will enhance negotiation and help to address the fundamental problem of high list prices and price increases.

Manufacturer Copay Discount Cards

HHS Solicits Feedback on:	<i>Should the current prohibitions around manufacturer copay discount cards and coupons continue; what changes should be implemented?</i>
AHIP Position:	<p>SUPPORT keeping the current Federal prohibition of manufacturer copay discount cards from Federal programs because coupons inappropriately increase the utilization of brand drugs.</p> <p>SUPPORT extending similar prohibitions to other markets (i.e., ACA plans, group health plans, employer-based plans).</p>
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • HHS should take steps to better prevent the use of discount cards and coupons in Federal health care programs by increasing accountability of manufacturers and third-party claim processors as well as by requiring a certain level of reporting and transparency to the Federal government. • Also, prescribers and pharmacists could be educated on the current restrictions on coupon use in federal health care programs. • For markets where discount cards and coupons are not currently prohibited, AHIP supports changes in law to limit the ability of manufacturers to induce utilization. <ul style="list-style-type: none"> ○ For example, discounts and coupons should be required to cover the patient’s entire out of pocket expenses for the duration of the drug therapy. ○ Manufacturers should be prevented from playing a game of “bait-and-switch” by limiting the coverage of a drug to a low amount that effectively pushes most costs to payers and other stakeholders.

Long-Term Financing of High-Priced Drugs

HHS Solicits Feedback on:	<i>Should consideration be given to long-term financing mechanisms for extraordinarily high-priced drugs?</i>
AHIP Position:	<p>OPPOSE. AHIP strongly recommends that HHS focus on strategies to reduce the cost of high-priced drugs, rather than consider strategies that effectively concede and encourage irresponsible manufacturer pricing practices.</p> <p>This is especially important given that extraordinarily high-priced drugs and therapies increasingly involve curative treatments that have not been studied in the long-term.</p>
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • Long-term financing models have been described and proposed by manufacturers as a “mortgage” for one’s health. Consumers are now being asked to carry payment obligations over multiple years, typically with little to no risk to manufacturers. • Long term payment mechanisms do nothing to address the fundamental threat of high list prices and price increases. In fact, we have serious concerns that facilitating such models would actually encourage higher manufacturer prices. • HHS should instead explore ways to reduce up-front costs by encouraging the development of payment arrangements that shift risk to manufacturers through reduced prices, with the potential for additional amounts to be paid on a graduated scale through value-based arrangements, but only to the extent the clinical data shows the effects of the treatments persist.

Rebates

Net Drug Costs & High Rebates	
HHS Solicits Feedback on:	<i>Do payers design and manage formularies or otherwise favor high rebates instead of low net drug costs?</i>
AHIP Position:	NO , AHIP’s members strongly favor and negotiate for low net drug costs for consumers, employers, government and other parties.
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • Health insurance providers operate in a competitive environment, attracting new customers through plans that deliver compelling value. They are strongly incentivized to negotiate low costs to offer more robust benefits and/or lower premiums and thereby attract more customers and enrollees. A plan’s success in lowering costs can determine its market share, competitiveness, and overall success. • AHIP members unequivocally support policies that would lower list prices and lower net costs. • Given the history of inflated list prices and price increases, including for products on the market well past their original market exclusivity period, and other questionable marketing and legal practices, we are highly skeptical that manufacturers will voluntarily change their industry culture and other business practices in a way that would lower prices in a true and sustained way.³ Assessments of the drug pipeline suggests prices will be an even bigger problem in the future.⁴ • If lower net costs ultimately can be achieved through lower list prices, AHIP would welcome a reduction in rebates. However, in the absence of substantially lower list prices for all pharmaceutical products, it is critical that payers continue to have access to all necessary market-based tools to reduce drug prices and costs such as negotiations for rebate payments.

³ “Humira’s Best-Selling Drug Formula: Start at a High Price. Go Higher.” January 6, 2018. <https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html>

⁴ Gene Therapy: Pipeline of Possibilities but Challenges for Pricing, January 25, 2018. <https://www.lexology.com/library/detail.aspx?g=7f317d05-abb-4919-b601-001b4cbc106d>

Rebates & List Prices

HHS Solicits Feedback on:	<i>Do higher rebates cause higher launch prices and list price increases?</i>
AHIP Position:	NO , we strongly disagree with the notion that high rebates contribute to manufacturers setting high list prices or prevent manufacturers from lowering list prices.
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • We believe that rebates neither contribute to high list prices set by drug companies nor prevent them from lowering list prices. • There are no assurances that lower rebates would lead to lower list prices. • The challenge of high drug prices has been documented for decades and came well before rebates were prevalent. Manufacturer pricing practices have also led Congress to intervene on numerous occasions. • Absent dramatically different drug company pricing practices, removing or severely limiting rebates likely will increase costs and impair patients’ access to affordable prescription drug coverage. • The focus on rebates distracts attention away from the true reason for high drug costs: drug companies’ ability to demand and command unreasonably high prices by taking advantage of a broken market. <ul style="list-style-type: none"> ○ Inflated list prices and price increases are what drive consumer costs, including copayments and premiums, and what drive costs for employers, governments, and other entities that pay for drugs. <ul style="list-style-type: none"> ▪ In fact, the Milliman report shows that the average annual cost per beneficiary for brand drugs with rebates was lower than for brand drugs without rebates. AHIP sees this as clear proof that the average annual cost per beneficiary for these drugs – which we understand effectively reflects list prices - are not driven by rebates. ○ The vast majority of drugs dispensed have no rebates. <ul style="list-style-type: none"> ▪ For example, the Milliman report found that nearly 90 percent of Part D drug claims were for drugs with no rebates. The Milliman report also found that, when measured on an individual drug basis (i.e., not a script count basis), approximately 70 percent of brand drugs did not have significant rebates – 64 percent of brand drugs had no rebates at all and 9 percent of drugs did not have significant rebates, where the percentage rebates were less than 12 percent. ○ Further, physician-administered drugs, which account for 30 percent of prescription drug spending, typically do not receive rebates.⁵ • Data show that the percentage of rebated drugs is decreasing and that list prices are also consistently rising whether drugs are rebated or not. <ul style="list-style-type: none"> ○ A recent HHS OIG report states: “Total reimbursement for all brand-name drugs in Part D increased 77 percent from 2011 to 2015, despite a 17-percent decrease in the number of prescriptions for these drugs [...] After accounting for manufacturer rebates, reimbursement for brand-name drugs in Part D still increased 62 percent from 2011 to 2015... In addition, the percentage of brand-name drugs for which manufacturers paid rebates decreased [over this period].”⁶ • The Milliman report found no clear correlation between percentage rebate levels and average price trends among brand drugs with rebates. However, the Milliman report shows that among drugs with rebates, the drugs with higher average annual cost per beneficiary had lower average percent rebates.

⁵ Trends in Specialty Drug Benefits, Pharmacy Benefit Management Institute, 2017.

⁶ Increases in Reimbursement for Brand-Name Drugs in Part D, Department of Health and Human Services’ (HHS) Office of Inspector General (OIG), June 2018. <https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf>

Rebates & “Fixed” List Prices

HHS Solicits Feedback on:	<i>Should HHS prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers and instead require that contracts be based only on a fixed list price for any particular drug over the contract term?</i>
AHIP Position:	<p>SUPPORT HHS goals for a simpler more transparent system that results in lower list prices and lower net drug costs.</p> <p>OPPOSE HHS eliminating or substantially reducing rebates for brand drugs (potentially through changes to the anti-kickback safe harbor) and instead require that negotiations focus on “fixed” pricing. Based on our limited understanding of the proposal, we have very serious concerns it could increase new risks on pharmacies, increase drug costs, and add administrative complexity.</p>
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • Based on our limited understanding of the proposal from its description, we assume that HHS may be envisioning a “fixed” price approach for brand drugs akin to the maximum allowable cost (MAC) system commonly used for generic drugs. • This system of chargebacks would pose significant and serious financial risks to pharmacies, such as cash flow problems between the time they buy and dispense extraordinarily expensive drugs and when they receive reconciliatory payments or credit from manufacturers. • This approach would require significant additional costs and create more complexities as the system would need to track and account for multiple “fixed prices” that would be negotiated by different payers for each drug. Moreover, despite these complexities, there would be no actual assurances for lower net drug costs. • Severely restricting or eliminating rebates could increase transparency for up-front discounts negotiated by drug companies, likely creating an even more anticompetitive pharmaceutical pricing environment and possibly increasing drug costs at a higher rate. • The adoption of value-based arrangements could be adversely affected if plans and manufacturers cannot negotiate retrospective payments based on agreed-upon metrics. • Legal concerns and questions also arise out of this policy. They include significant questions under anti-trust laws such as the Robinson-Patman Act and the noninterference clause, a critical feature of the Medicare Modernization Act of 2003 and Part D program.⁷ Moreover, though the anti-kickback statutory exception for drug discounts would still remain if HHS scaled back or eliminated the anti-kickback safe harbor rules, such an act by HHS would likely create confusion, raise legal and financial risks, and substantially increase legal and financial costs for a range of stakeholders. This would also have a chilling effect on competitive negotiations between plans and manufacturers, leading to higher drug costs. Thus, rather than reduce administrative burdens and costs, a clearly stated goal of the Administration, it would instead significantly increase burdens and costs. • If HHS were to move forward with this approach, it would be critical to provide sufficient lead time to allow for plans to evaluate the impacts, negotiate contract changes, and properly incorporate them into their products – especially critical for Part D given its reliance on an annual plan bidding process.

⁷ In 2003, CBO recommended against removal of the noninterference clause and estimated that “substantial savings will be obtained by the private plans and that the Secretary would not be able to negotiate prices that further reduce federal spending to a significant degree. Because they will be at substantial financial risk, private plans will have strong incentives to negotiate price discounts, both to control their own costs in providing the drug benefit and to attract enrollees with low premiums and cost-sharing requirements.” <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/fristletter.pdf>

Point of Sale (POS) DIR Concessions – Manufacturer Rebates

HHS & The White House Has Proposed:	<i>Should Part D sponsors be required to incorporate manufacturer rebates into the negotiated rate as point of sale for drugs that receive rebates?</i>
AHIP Position:	OPPOSE POS concession of manufacturer rebates as they would ultimately negatively impact virtually all/most beneficiaries’ access to prescription drug coverage by increasing premiums for over 43 million seniors and by delivering to drug companies increased leverage to raise prices of branded drugs with rebates.
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • Such a proposal would do nothing to impact the fundamental problem of high list prices and the drug industry’s ability to unreasonably set and increase them. • To the extent HHS continues to consider the Part D point-of-sale (POS) RFI that CMS published in the <i>Federal Register</i> on November 28, 2017, AHIP reiterates the substantial concerns from our previous comment letter: <ul style="list-style-type: none"> ○ Higher premiums for beneficiaries – the Administration itself estimated government and taxpayer costs would increase an estimated \$40 billion over 10 years, ○ Ability of manufacturers to reverse engineer rebates negotiated by their competitors and thereby increase prices, ○ Small and narrow distribution of benefit among beneficiaries, ○ Promoting the use of more expensive branded products over their generic competitors, and ○ Running afoul of the non-interference clause. • Additionally, LIS beneficiaries pay small copayments rather than a coinsurance would not materially benefit from this policy.

PBM Compensation Arrangements & Legal Obligations

PBM Fees & Fiduciary Duty	
HHS Solicits Feedback on:	<p><i>Should HHS prohibit PBMs from receiving payment or remuneration from manufacturers, or prevent PBM fees from being calculated as a percentage of list price?</i></p> <p><i>Should HHS require PBMs to act as a fiduciary?</i></p>
AHIP Position:	<p>OPPOSE new government restrictions on private sector compensation arrangements.</p> <p>OPPOSE imposing a fiduciary duty on PBMs.</p> <p>HHS should NOT pursue new levels of government interference in private contracting arrangements.</p>
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • Such new levels of government interference are unnecessary. Health insurers are incentivized to obtain low net drug costs to create more robust benefits and/or reduced monthly premiums, in alignment with the goals of consumers and other purchasers. If a plan’s selected PBM cannot deliver satisfactory results, the plan has options, including the selection of an alternative PBM. • Government attempts to structure compensation arrangements may ultimately increase rather than decrease costs. The limitation on how PBMs can be compensated and/or imposition of new legal liabilities will likely result in higher drug costs and administrative costs being passed on to consumers through higher monthly premiums and reduced benefits. • Such restrictions raise significant legal questions. For example, the question of how PBMs would be allowed to negotiate with manufacturers on behalf of plans and how the non-interference clause would apply in Medicare Part D are still open questions. • Government restrictions on private sector compensation arrangements could have a broader precedential impact. For example, the creators of Medicare Part D recognized the importance of protecting negotiations from government interference. HHS should avoid creating such an interference of private party negotiations and contracting. • Rather than attempt to reengineer various processes associated within the drug distribution system, including compensation arrangements, HHS should instead remain focused on outcomes involving cost and value.

Medicaid Best Price

Best Price & Medicaid Drug Rebate Program	
HHS Solicits Feedback on:	<i>Does the Medicaid Best Price requirement pose a barrier to better price negotiation and certain value-based arrangements?</i>
AHIP Position:	YES , the best price requirement does pose a barrier to price negotiation in the commercial market and certain value-based arrangements. In addition, while other components of the Medicaid Drug Rebate Program (MDRP), including relevant changes made in the ACA, provide savings for state budgets, HHS should encourage greater use of existing tools and increased flexibility so state Medicaid beneficiaries use the lowest cost clinically appropriate drugs.
Key Considerations & Recommendations:	<ul style="list-style-type: none"> • Data indicate that coverage programs exempt from best price, like Medicare Part D, obtain larger rebates than coverage subject to best price. • Best price does not appear to be providing additional rebates to the Medicaid program to any material degree. • While best price is a statutory requirement, HHS can take steps within its regulatory authority to limit adverse impacts. For example, AHIP recommends that HHS issue guidance providing that certain types of value-based arrangements between manufacturers and payers do not implicate best price. • Best price should be distinguished from the other components of the Medicaid Drug Rebate Program that provide minimum percentage rebates and supplemental rebates for prices increases. • Until the lack of competition, transparency, and accountability in the prescription drug market is addressed, the rebate percentage component of the Medicaid rebate program is important for state and federal government budgets, particularly with respect to high price drugs without competition that ordinarily do not generate rebates. We also note the importance of changes made by the Affordable Care Act (ACA) to extend rebates to drugs obtained by enrollees in Medicaid Managed Care plans. These plans cover a substantial and ever-increasing percentage of Medicaid enrollees. The law must ensure parity for states increasingly using managed care to provide Medicaid benefits. • AHIP supports HHS’ development of proposals to address the change made in the ACA that limits the maximum rebate to 100 percent of the Average Manufacturer Price (AMP). • However, minimum rebates do not solve the problem of increasing drug costs. Accordingly, there must be a continued focus on changes to the competitive environment so that drug costs reflect vigorous competition and good faith negotiation. • In addition, studies demonstrate problems with the existing rebate structure. For example, some states are not optimizing savings by using mechanisms to encourage the lowest-cost clinically effective drug products.⁸ Research shows that the costs per prescription of

⁸ For example, a 2015 study by the Menges Group <https://www.ahip.org/wp-content/uploads/2015/11/Medicaid-Pharmacy-Carve-In-Final-Paper-The-Menges-Group-April-2015.pdf> found that states using Medicaid managed care plans to encourage greater use of generics and lower-cost drugs had net prescription costs 14.6 percent lower than states “carving out” drugs from managed care. This translated into over \$2 billion net savings in state and federal expenditures in 2014.

See also: https://www.themengesgroup.com/upload_file/louisiana_carve_out_report_may_2018.pdf

brand drugs, net of rebates, is more than nine times the cost per prescription of generic agents.⁹

- We urge HHS to take steps to encourage states to use utilization management criteria and tools already being effectively used in some states (and commonly used outside of Medicaid) to increase reliance on generic drugs rather than brand-name drug rebates.
- In addition, states and Medicaid health plans should be allowed to use more restricted formularies and value-based arrangements (e.g., through demonstrations), similar to flexibilities available for commercial health plans and Part D.

⁹ https://www.themengesgroup.com/upload_file/louisiana_carve_out_report_may_2018.pdf