April 8, 2019

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

Mr. Daniel R. Levinson
Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201


Dear Secretary Azar and Mr. Levinson:

America’s Health Insurance Plans (AHIP) appreciates the opportunity to comment on this Proposed Rule, which would overhaul safe harbor protections under the federal anti-kickback statute for discounts relating to prescription drugs and for pharmacy benefit manager (PBM) service fees. AHIP is the national association whose members provide coverage for health care and related services for millions of Americans. Our members include Medicare Advantage, Part D, and Medicaid managed care coverage providers that work hard to negotiate lower drug prices for the millions of consumers we serve. The bargaining our members and their PBM partners employ on behalf of beneficiaries lowers their premiums, the costs they pay at the pharmacy counter, and their tax contributions for government programs.

Patients deserve affordable access to life-saving drugs. Everyone agrees: Prescription drug prices are out of control. That’s because drug makers alone set outrageous launch and list prices. They alone have the power to raise those prices – putting access for patients at risk. And they alone have the power to reduce those prices.

We share – and applaud – the Administration’s commitment to lowering drug prices and reducing out-of-pocket costs. We need real solutions to ensure that every patient can get the medications they need at a price they can afford. We also believe there are legitimate concerns regarding the complexity of the current drug pricing system. Accordingly, we want to work with the
Administration on policy solutions that will encourage innovation and help patients and consumers pay less.

However, we have serious concerns about the real-world ramifications of the Administration’s Proposed Rule and whether it will have the intended effect of reducing drug prices. We also have concerns that the Proposed Rule will ultimately result in higher drug costs and higher premiums for tens of millions of Medicare beneficiaries who rely on fixed incomes, in addition to fewer benefit choices. Further, if the Department of Health and Human Services (HHS) finalizes its proposed 2020 effective date, we have concerns about the likelihood of significant operational challenges associated with moving to a new system with little time to rigorously test the system, especially given the potential application of both criminal and civil/administrative penalties under the anti-kickback statute.

We do appreciate the April 5 memorandum released by Administrator Verma, which responds to the potential for serious short-term instability in the program given the looming 2020 Part D bid deadline. It provides important bidding guidance related to the Proposed Rule. We further appreciate the memorandum’s announcement that plans will be able to rely on a new Centers for Medicare & Medicaid Services (CMS) demonstration program involving Part D risk corridors if there is a change in the safe harbor rules for 2020. However, while we are still reviewing the memorandum, it clearly will not solve the fundamental problems with HHS’ proposed changes to the safe harbor rules and the potential criminal and civil liabilities associated with the removal of the current safe harbor, the large premium increases over time, and the new burdens on taxpayers to finance higher payments to drug makers.

**Bigger and Bolder Drug Pricing Solutions Are Needed for All Americans**

We want to be perfectly clear: Health insurance providers are not committed to rebates in any way, shape or form. We are committed to getting the lowest drug prices and costs for patients and consumers. This includes what they pay out-of-pocket at the pharmacy counter, in premiums, and in taxes. Any proposal that raises costs in any of these areas would simply force consumers to pay higher prices for prescription drugs out of a different pocket.

While the Proposed Rule is well intentioned, its piecemeal focus on how Medicare Part D and Medicaid managed care insurance providers and their contracted PBMs negotiate with drug makers will make the problem of high drug prices and costs even worse. AHIP urges the Administration to move beyond a narrow focus on rebates and to work with us, our members, and other stakeholders on delivering bold solutions that will help all Americans.

We have developed a five-point package of proposals to tackle the problem of high drug prices. Our package includes meaningful, market-wide solutions, including legislative actions, which go far beyond the Proposed Rule’s limited focus on rebates. As part of this comprehensive package, we are prepared to work constructively with the Administration, the Congress, and other stakeholders on alternatives to the current rebate system.
Our alternative framework includes the following five components:

1. **Ensure effective private-sector negotiation.** Allow health insurance providers and their contracted PBMs to expand private-sector leverage to deliver greater competition, choice, and the lowest possible costs for patients and consumers.

2. **Eliminate barriers to implementation.** Remove legal barriers to lower prices and government regulation, including long-standing antitrust concerns that were a major contributor to the development of the rebate system in the first place.

3. **Restrain drug costs during the transition.** Mechanisms need to be in place during any transition to a new structure and going forward to ensure money that consumers could save does not instead go into drug makers’ pockets. Those mechanisms should include robust oversight of drug makers by CMS.

4. **Provide a meaningful transition period.** Provide an appropriate transition period — no earlier than 2022 — to ensure a successful implementation. With its recent guidance to Part D plan sponsors about a new two-year demonstration program to modify the program’s risk corridors for 2020 and 2021, CMS appears to recognize one of the potential serious problems with a 2020 implementation date. It is critical that development and testing of costly new systems and capabilities, resource-intensive changes to a multitude of contracts, and a range of other operational steps take place before disruptive changes that could affect enrollees and other stakeholders are implemented in the Part D program.

5. **Address the root cause of high drug prices.** Any changes in the structure affecting discounts should be part of a broader package designed to solve the root cause of high drug prices: the fundamental lack of market competition and gaming of the system by drug makers that are blocking patient and consumer choice. Such comprehensive efforts could include stopping drug maker games that limit entry by new generic and biosimilar competitors; ensuring federal rules promote the availability of interchangeable biosimilars; revising market exclusivity periods and orphan drug incentives; providing more transparency and timely information about drug and biologic patents to promote greater generic drug and biosimilar competition; requiring drug makers to publish true research and development costs and explain price setting and price increases; mandating that drug maker coupons and/or co-pay cards cover a patient’s entire out-of-pocket expenses for the duration of the drug therapy; disclosing list prices in direct-to-consumer advertisements; informing patients and physicians on effectiveness and value; eliminating barriers to value-based pricing; and exercising HHS authority to introduce market competition when manufacturers fail to engage in reasonable, good-faith negotiations with payers.

**Proposed Rule Misses the Core Problem: High-Priced Drugs Without Competition**

The exclusive focus on rebates is a distraction. Branded drug prices are high, not because of the savings negotiated by health insurance providers and PBMs, but because the highest priced drugs have no real competition. CMS data show how the largest spending increases in Medicare and Medicaid are driven by drugs with NO competition. For example, in 2017, the top 50 highest cost Part D drugs (ranked by total program spending) represented only 1.7 percent of all Part D drugs...
prescribed but 42 percent of total Part D spending. Of these top 50 highest cost drugs, nearly all (92 percent) had no competition from other drug makers.\(^1\)

When no competing products exist, drug makers of branded drugs have no incentive to and rarely offer discounts or rebates. In addition, most other drugs covered by Part D offer no rebates, as HHS reported that 86 percent of Medicare Part D prescriptions in 2016 were for generic drugs.\(^2\) Moreover, evidence shows that the percentage of “rebated” drugs is decreasing.\(^3\) And the problem is likely to get worse given the drugs in the development pipeline that will be protected from competition by patent monopolies and carry extraordinarily excessive price tags.

However, where competition does exist, health insurance providers and PBMs negotiate effectively with drug makers to obtain substantial discounts in exchange for preferred formulary placement and lower patient cost-sharing. If we didn’t negotiate on behalf of patients, drug prices would be far higher for patients and the costs to consumers far worse.

And yet, even with rebates, rising drug prices are leading to higher costs. For example, the Office of Inspector General has found that: “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…”\(^4\)

The Proposed Rule ignores these facts and instead:

- Suggests rebates are the cause of high drug prices.
- Proposes to create a more complex, untested, and vastly different pricing structure.
- Requires that changes be operationally implemented within an unrealistic 2020 timeline without meaningful time to ensure adequate testing.
- Limits our members’ private-sector negotiating leverage while keeping long-standing legal barriers in place that block alternatives to rebates.
- Fails to hold drug makers accountable to lower their prices.
- Imposes unfair and unnecessary costs for states using Medicaid managed care plans as Medicaid beneficiaries already face little or no co-payments for their drugs. This would create an unlevel playing field that could cause some states to consider less cost-effective options for managing their drug benefits.

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\(^4\) Ibid.
All this will make the problem of high drug costs even worse by strengthening drug makers’ ability to control the prices they set, weakening negotiating leverage for plans and PBMs to obtain lower prices, and ultimately raising costs for enrollees and taxpayers.

**Proposed Rule Would Increase Costs for Seniors and the Government but Provide a Windfall to Drug Makers**

While a small percentage of Medicare patients may get some limited relief at the pharmacy counter, every senior and Medicare beneficiary covered by Part D will pay higher premiums and/or receive fewer additional benefits. All hardworking taxpayers will bear the burden of higher government spending in Medicare and Medicaid. According to CMS’ own expert actuaries (the Office of the Actuary, or OACT), eliminating rebates over several years will:

- Increase Medicare premiums for seniors by 25 percent or $58 billion,
- Increase Medicare drug spending by $196 billion, and
- Give drug makers a $100 billion windfall in new revenue, including reducing their coverage gap discount program liability by almost $40 billion.

However, the actual negative impacts from this Proposed Rule may be much larger than what OACT has estimated because drug makers could keep more than 15 percent of current rebate dollars as additional revenue. According to an AHIP-commissioned analysis by Avalere Health, who replicated OACT’s assumptions and modeled the impacts on premiums and government costs, if drug makers retained 50 percent of current rebates:

- **Government spending** would increase more than twice as much as OACT estimated, or nearly half a trillion dollars over a 10-year period – $410 billion.
- **Beneficiary premiums** would increase an estimated $85.7 billion, or nearly 40 percent.

We note this effort by HHS to improve the Part D program could in fact cost nearly as much as the Congressional Budget Office estimated that creating the entire Medicare Part D program would cost. In addition, out-of-pocket spending, on average, could actually increase for seniors, which would run counter to HHS’ goal of lowering out of pocket costs.

Millions of Americans served by Medicare Advantage and Part D plans, and states providing Medicaid through cost-effective, high-quality managed care plans, would face these higher costs. More than 45 million seniors and persons with disabilities have chosen to enroll in Part D plans, which help them afford their prescription drugs while delivering high rates of quality, value, and beneficiary satisfaction. They include almost 20 million in Medicare Advantage plans that integrate

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Part D coverage, who could face higher premiums and/or reduced supplemental benefits under the Proposed Rule, and more than 25 million in stand-alone Part D plans.

Medicaid is also an essential part of American health care. Two-thirds of Medicaid enrollees – about 55 million Americans – are served by Medicaid managed care plans that work with states to control costs and improve value, providing high-quality access to care while saving billions of taxpayer dollars by streamlining services. However, the Proposed Rule would, according to OACT’s estimates, increase state and federal costs for Medicaid by $2 billion.

**Withdraw the Proposed Rule and Pursue Better Approaches**

Given the uncertainties, costs, and serious risks to patients, consumers, and states, *HHS should reconsider its proposed changes to the rebate structure and withdraw the Proposed Rule*. The Administration should consider alternatives as part of a bigger, bolder reform package that AHIP has outlined, including many elements of American Patients First Blueprint. However, if the Administration insists on moving forward with its limited approach, we urge HHS to seriously consider several steps relating to Part D that we outline in our attached comments to promote HHS’ goals within the existing system, including targeting cost-sharing relief for enrollees taking very high-priced drugs. Importantly, these proposals would avoid simply shifting money from patients and taxpayers to drug makers.

The roots of the American drug pricing problem are extraordinarily deep and have grown from seeds of legislative and regulatory policy planted over decades that have warped the economic balance in favor of pharmaceutical manufacturers over patients, payers, and hardworking taxpayers. This problem is bigger than can be addressed in one rule. It is bigger than rebates, and it’s bigger than Medicare Part D and Medicaid managed care. Simply, the problem is the price. We call on the Administration to work with us, the Congress, and other stakeholders genuinely interested in reducing drug prices on a comprehensive approach. Whether it involves incremental changes to upfront discounts or a major alternative to the entire rebate system, it must be a real solution that enables the private sector to negotiate fair prices and lower costs for all Americans.

Sincerely,

Matthew Eyles
President and CEO

I. OVERVIEW

A. Summary of AHIP Position

AHIP supports the Administration’s goals of lowering prescription drug prices and reducing out-of-pocket costs for patients and consumers. We and our members stand ready to work with the Department of Health and Human Services (HHS) to consider a bold package of statutory and regulatory changes to achieve these goals. Such an approach could include changes in the discount structure, but only if they are meaningful improvements over the current structure, are not cost-inhibitive, enhance competition, and lower the underlying cost of drugs. To accomplish those goals, any such changes must give health insurance providers and their contracted pharmacy benefit managers (PBMs) the tools to negotiate discounts, have reasonable implementation timelines, address legal and operational barriers, and have mechanisms to ensure the system will reduce costs rather than shift funds to drug makers. This comment letter includes our bold package of recommendations to improve affordability and help further these goals.

The Proposed Rule, by contrast, is a half-measure that would harm many seniors and people with disabilities who are enrolled in Medicare Part D plans. The proposed changes focus exclusively on eliminating the current rebate structure despite extensive evidence that the biggest cost driver in our current system, including Part D, is spending for expensive brand drugs that lack meaningful competition and offer no material rebates. It includes unworkable timelines that will not allow for adequate design, testing and support for a new, complex and untested system. It fails to address serious legal barriers to implementing the structure. It imposes new limits on the ability of health insurance providers and their PBMs to negotiate discounts while failing to include any mechanisms to prevent drug makers from gaming the new system. And it threatens serious criminal and civil penalties for complying with standards that are vague and uncertain. By failing to address underlying causes or the critical implementation challenges and barriers, the Proposed Rule will end up increasing premiums and government costs and prevent HHS from reaching its goals.

In fact, we believe these defects will cause premiums and government costs to increase over the next decade even more than the government’s own estimated growth of 25 percent and almost $200 billion, respectively. An AHIP-commissioned Avalere analysis, in which AHIP asked Avalere to model a scenario where only 50 percent of current pricing concessions are passed through to the point-of-sale, shows that premiums could go up by nearly 40% and that government spending could increase by $410 billion if drug makers offer even smaller discounts.

Higher Part D premiums do not only hurt enrollees in stand-alone Part D plans. The 19.5 million Medicare Advantage (MA) enrollees who have Part D coverage could see their plan premiums rise, have access to fewer supplemental benefits, or both. Dually eligible and other low-income Medicare
enrollees – estimated to be 13.6 million in 2020\(^6\) – who receive coverage through MA plans, including Special Needs Plans (SNPs), and through Medicare-Medicaid Plans demonstration plans (MMPs), could also see fewer available benefits.

*Separately, we strongly oppose the application of the proposal to Medicaid managed care organizations (MCOs).* It would provide no benefit to enrollees, since they already pay little or no costs for drugs. It would also impose unnecessary costs on states using Medicaid managed care, creating an unlevel playing field that could cause some states to consider less cost-effective options for managing their drug benefits.

*If HHS is not prepared to take our recommended bold steps, the Department should, nonetheless, withdraw the rule and continue to allow the use of rebates.* Instead, HHS should consider a package of specific regulatory proposals that would work within the existing structure to address its key goals without harming consumers.

Our comments and recommendations are described in more detail below.

**B. Summary of Proposed Rule**

As we understand the Proposed Rule, HHS would make three significant changes to the safe harbor regulation under the federal anti-kickback statute for discounts relating to prescription drugs. First, HHS proposes to amend 42 CFR §1001.952(h)(5) by removing anti-kickback safe harbor protection for “a reduction in price or other remuneration” paid by a drug manufacturer for the sale or purchase of a prescription drug to Part D plans, Medicaid MCOs, or their contracted PBMs, “unless it is a price reduction or rebate that is required by law.” HHS proposes for this change to be effective on January 1, 2020.

Second, HHS proposes to create a new safe harbor under 42 CFR § 1001.952(cc) for manufacturer discounts negotiated by a Part D plan, Medicaid MCO, or their contracted PBM if three conditions are met. The price reduction must be set in advance and disclosed in writing before the initial purchase of the product by the plan or PBM. The full value of the discount must be provided by a manufacturer to a pharmacy through a chargeback or series of chargebacks, defined as a payment made directly or indirectly by a drug manufacturer to a pharmacy such that the total pharmacy payment is equal to or greater that the price agreed upon by the plan or PBM and the drug manufacturer. And any reduction in price must be completely applied to the price charged to the beneficiary at the point-of-sale.

Lastly, HHS proposes to create a new safe harbor that would protect fees paid by a manufacturer to a PBM for services rendered. There must be a written agreement with the drug manufacturer that specifies the services provided by the PBM and the compensation associated with those services. The

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fee must be consistent with fair market value and an “arm’s-length transaction”; a fixed amount (rather than based on a percentage of sales); and an amount that is not dependent on the volume, value, or business generated by the arrangement, payable in whole or in part by Part D or Medicaid. The PBM must also disclose, in writing, the services that it renders to each drug manufacturer to all plans it contracts with annually and to HHS upon request.

HHS indicates that the changes are designed to better align incentives to curb list price increases, reduce financial burdens on enrollees, improve transparency, and reduce the likelihood that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid MCOs.7

The Proposed Rule also provides several estimates of the financial impacts of the proposals. The official HHS analysis from CMS Office of the Actuary (OACT) estimates that government costs for the Part D program will increase by almost $200 billion and that Part D premiums will increase by 25 percent over the next 10 years if the proposal is finalized. OACT also estimates that state and federal costs for Medicaid would increase by $2 billion. Though OACT estimates that the overall average cost-sharing amount would decrease, the majority of enrollees would see an increase in total out-of-pocket spending, which includes both cost-sharing and premiums. Drug makers’ coverage gap discount program liability would also decrease by almost $40 billion and there would be an estimated boost in total drug spending of $137 billion.8

II. FUNDAMENTAL PROBLEM: HIGH LIST PRICES – NOT RebATES

As we clearly stated in our comments to the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (“Blueprint”), health insurance providers unequivocally support lower list prices. However, the drug industry’s persistent and egregious behavior over the past four decades undermines a core premise of the Proposed Rule: that high rebates contribute to high list prices and price increases, and that, therefore, removing rebates from the system would lead to lower prices.

Rebates neither contribute to high list prices set by drug makers nor prevent drug makers from lowering list prices. Rebates are, instead, used as a market-based mechanism to counter drug maker pricing practices. For example, Part D rebates have been effective in reducing costs for enrollees through lower premiums9 and will likely continue to reduce costs for enrollees. Simply removing rebates creates no mechanism nor assurances that lower list prices would follow. We are concerned that the Proposed Rule simply diverts attention away from the true reason for high drug costs: drug makers’ ability to demand and command unreasonably high prices by taking advantage of a broken market.

89 www.hhs.gov/cfda.gov/ows/event/0591/OACTProposedSafeHarborRegulationImpacts.pdf
A. Drug Maker Behavior

The problem of high list prices is not new. Drug makers’ practice of setting high drug prices and increasing them unreasonably is an intentional, persistent, and pervasive decades-long drug industry strategy to maximize profits.\(^\text{10}\) In response, Congress has had to take numerous actions to address this issue, with each effort focused on fixing a broken part of the market. For example:

- In 1984, Congress passed the bipartisan Hatch-Waxman Act, to reduce drug prices by infusing the market with robust generic competition.\(^\text{11}\)
- In 1992, Congress passed the Omnibus Budget Reconciliation Act of 1990, to create the Medicaid Drug Rebate Program so that state budgets may find some relief from high list prices.\(^\text{12}\)
- In 2003, Congress passed the bipartisan Medicare Modernization Act of 2003 (MMA), to allow plans to offer seniors and persons with disabilities affordable access to prescription drugs by creating the Medicare prescription drug coverage program (Part D).\(^\text{13}\)
- In 2010, Congress passed the Biologics Price Competition and Innovation Act of 2009, to help reduce prices of biologics by infusing the market with competition from biosimilars and eventually interchangeable biologics.\(^\text{14}\)
- In 2010, Congress passed the Patient Access and Affordable Care Act, to require drug makers to pay for part of Medicare enrollees’ cost-sharing in the coverage gap phase by creating the Coverage Gap Discount Program.\(^\text{15}\)


\(^{12}\) 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


\(^{14}\) CBO estimated that the federal government would save $25 billion over 10 years due to savings from lower prices gained by a robust biosimilar market. https://www.cbo.gov/publication/24808

• In 2018, Congress passed the Bipartisan Budget Act of 2018 (BBA), to increase the responsibility drug makers have for brand drug and biosimilar spending incurred during the coverage gap phase.\textsuperscript{16}

Egregious drug maker behavior continues to the present day, even in the face of Administration efforts to lower prices. Despite some drug makers agreeing to freeze prices in 2018 after being put under pressure by the Administration, they quickly returned to their routine strategy of raising prices at the start of this year.\textsuperscript{17} As drug makers historically do twice a year in January and July,\textsuperscript{18} they decided, once again in January 2019, to raise prices on hundreds of drugs by an average of 6.3 percent.\textsuperscript{19} In fact, we have seen more drug price increases this year than in past years, as drug makers are likely trying to “to catch up on delayed hikes from 2018.”\textsuperscript{20} Below, we discuss the impact of the drug industry’s egregious pricing practices on Part D spending and growth.

B. Key Data

1. List Prices Drive Up Part D Spending and Drug Costs

Data and analyses from numerous sources demonstrate that list prices — not rebates — are driving drug spending.

\textit{a. Medicare Payment Advisory Commission Findings}

The Medicare Payment Advisory Commission (MedPAC) found that most of the overall growth in Part D spending comes from increased average prescription prices for high-cost enrollees (i.e., enrollees who reach the catastrophic phase of the Part D benefit).\textsuperscript{21} Between 2007 and 2017, list prices for a small number of single-source brand drugs lacking cheaper alternatives increased by 195 percent. While these drugs account for only 13 percent of prescriptions filled in 2016, their spending overwhelmed the savings gained from high Part D generic utilization.


\textsuperscript{21} Medicare Payment Advisory Commission, Report to the Congress: Medicare payment policy, March 2019.
b. Centers for Medicare & Medicaid Services Findings

Consistent with MedPAC’s findings, data in the recently updated Centers for Medicare & Medicaid Services (CMS) Drug Spending Dashboard shows how the biggest spending increases in Medicare and Medicaid are being driven by a few high cost drugs that lack competition, a problem that is likely to worsen.22,23

In 2017, the top 50 highest cost Part D drugs (ranked by total program spending) represented only 1.7 percent of all Part D drugs prescribed but 42 percent of total Part D spending. Of these top 50 highest cost drugs:

- Nearly all (92 percent) had no competition from other drug makers,
- More than a third (35 percent) increased in average unit dose24 spending by more than 10 percent,
- More than half (62 percent) had an increase in average per enrollee spending of more than 10 percent, and
- Almost half (40 percent) would drive an enrollee taking only that one drug into the catastrophic phase by the end of the Part D coverage year, with 22 percent automatically driving an enrollee into the catastrophic phase with only one prescription.

c. Congressional Budget Office Findings

The Congressional Budget Office (CBO) recently released a report on specialty drug use, cost, and pricing under Medicare Part D.25 The CBO report found that in 2015, brand-name specialty drugs accounted for about 30 percent of spending on prescription drugs net of rebates under Medicare Part D, but only accounted for 1 percent of all prescriptions dispensed. CBO also found that the growth in Medicare Part D spending net of rebates on specialty drugs from 2010 to 2015 was driven by the high launch prices for new drugs introduced after 2010 and a shift in utilization towards drugs with higher prices. Namely, using a price-index approach, the average net price per prescription of brand-name specialty drugs in Medicare Part D grew by 5.8 percent. After considering the shift towards higher priced drugs, the average net price per prescription of brand-name specialty drugs grew by

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24 CMS defines the dosage unit as the drug unit in the lowest dispensable amount (e.g. number of tablets, grams, milliliters or other units).

22 percent. The average net price per prescription of new brand-name specialty drugs was $8,680 in 2015 in comparison to $2,570 for drugs on the market prior to 2010.

d. HHS Office of Inspector General Findings

The Office of Inspector General (OIG) found that from 2011 to 2015, gross total Part D drug spending on all brand drugs increased by 77 percent, while the number of prescriptions for these drugs fell by 17 percent. Over the same period and after accounting for rebates, the net total Part D spending for all brand drugs still increased by 62 percent.26

2. Most Part D Drugs Dispensed Have No Rebates, and the Proportion that Do Is Falling

Rebates are irrelevant to most drugs covered by Medicare Part D, which further indicates that drug prices, and not rebates, should be the key focus for the Administration.

- A recent Milliman study found that nearly 90 percent of Part D drug claims in 2016 were for drugs with no rebates. The 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.27
- The OIG found that the percentage of brand-name drugs for which manufacturers paid rebates decreased between 2011 and 2015.28
- HHS has reported that 86 percent of Medicare Part D prescriptions in 2016 were for generic drugs, which typically have no rebates.

Because most drugs and the vast majority of prescriptions in Medicare Part D do not have any rebates, OACT estimates that the Proposed Rule would fail to provide net out-of-pocket savings for the majority of Part D enrollees. (In fact, as noted elsewhere, when premiums are considered, net costs would increase for most people.)

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3. For Part D Drugs with Rebates, Many Enrollees Taking those Drugs are Unaffected by a Point-of-Sale Policy

In 2020, an estimated 13.6 million low-income enrollees, roughly 28 percent of total estimated Part D enrollees, will be enrolled in stand-alone drug plans, MA plans, MMPs, and other types of arrangements with Part D coverage. They will receive cost-sharing assistance through the low-income subsidy (LIS) program. Of those enrollees, 13.3 million full subsidy-eligible individuals will have no deductible, will pay a maximum (or lower, depending on income) of $3.60 for generic or preferred multiple source brand drugs, and $8.95 for other brand drugs, and have no cost-sharing liability after meeting the annual out-of-pocket threshold in 2020. For such beneficiaries, the Proposed Rule offers no material benefit, and in fact could harm them by reducing funds available for MA supplemental benefits.

In 2020, 400,000 low income enrollees will be eligible for partial subsidies and will receive premium assistance on a sliding scale ranging from 100 percent to 25 percent of the premium. As such, they could suffer significant hardship from higher premiums.

4. For Drugs with Rebates, Rebates Do Not Drive List Prices

Drug makers have sole control over setting and increasing (or decreasing) list prices. It is wrong to suggest that rebates drive list prices.

The Milliman study found no clear link 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 enrollee ($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, the non-specialty/non-protected class drug average rebate percentage (35 percent) was higher than the average rebate percentage for specialty drugs (24 percent) and protected class drugs (14 percent). The Milliman report also shows that the average annual cost per enrollee for brand drugs with rebates was lower than for brand drugs without rebates in 2015 and 2016.

We believe this is proof that the average annual cost per enrollee for these drugs, which reflects list prices, is not driven by rebates.

30 See footnote 6.
31 Ibid.
32 Ibid.
5. This Problem is Likely to Get Worse

According to the 2018 Medicare Trustees Report, Part D spending increased overall by 7.4 percent annually and 3.8 percent per capita over the past 10 years. In the future, the Trustees expect per capita Part D drug spending to exceed the growth rate for other categories of medical spending as the generic utilization rate slows and spending on specialty drugs continues to increase.33

III. IMPLEMENTATION CHALLENGES OF RULEMAKING

If HHS were to move forward with the Proposed Rule, a multitude of implementation challenges would prevent the Department from achieving its stated goals and instead would significantly increase costs.

A. The Proposed 2020 Effective Date Makes the Rule Unworkable

HHS proposes to sunset current safe harbors for prescription drug rebates paid to Part D plans, Medicaid MCOs, and their contracted PBMs under 42 CFR 1001.952(h) by January 1, 2020. This would eliminate the use of rebates for the 2020 plan year and would force stakeholders to rely on a chargeback system. However, this timeline is not workable. Based on feedback from our members, we believe the operational challenges alone would require delay until 2022 at the earliest.

Separately, the timing of the Proposed Rule process itself has raised serious concerns given the looming June 3, 2019 Part D bid submission deadline for 2020. We appreciate the April 5 memorandum released by Administrator Verma provides bidding guidance related to the Proposed Rule and announces that CMS will offer a demonstration program relating to Part D risk corridors if there is a change in the safe harbor rules for 2020. Given the timing and absence of details in the guidance, we are still reviewing and assessing its impacts. We urge the Administration to engage collaboratively with plans to ensure the guidance and demonstration program will adequately protect Part D if the Proposed Rule is finalized for 2020. Further, while the memorandum addresses one critical short-term issue, the memorandum will not solve the fundamental problems with HHS’ proposed changes to the safe harbor rules, including large premium increases over time and new burdens on taxpayers to finance higher payments to drug makers.

1. Proposed Timeline Fails to Account for the Costs and Complexity of Proposed System

The chargeback system that appears to be envisioned under the Proposed Rule would require significant additional costs to implement and would be a far more complicated system than what currently exists. For example, this system would appear to require that each pharmacy be able to track and account for the multiple discounts that would be negotiated by different payers for each drug the pharmacy dispenses. That way, the pharmacy could be reimbursed by drug makers for the appropriate level of discount after the point-of-sale transaction.

33 Ibid.
This complex system would require a tremendous amount of development and coordination among all Part D stakeholders (e.g., Part D plans, PBMs, pharmacies, drug makers, wholesalers, information technology and software vendors, patients, and HHS). In addition, stakeholders would need to renegotiate existing contracts and develop a host of new contracts, which would necessarily be a time-consuming and resource-intensive process.

Once the infrastructure is designed, it would need to be rigorously tested to avoid serious adverse impacts on pharmacies and potentially other stakeholders. The importance of adequate design and testing for major structural changes in health care has been illustrated numerous times, including the successful roll-out of Part D and the more challenging roll-out of the individual market Exchanges. Further, even assuming a chargeback system can be successfully implemented by 2020, the Proposed Rule does not contemplate any government oversight or clear assignment of accountability. In contrast, Part D plans must comply with rigorous oversight and accountability standards under the current system.

2. Part D Bid Deadline Raises Key Concerns

AHIP has had serious concerns about the tremendous uncertainty HHS arbitrarily injected into the 2020 bid development process because of its decision to initiate a significant regulatory proposal so close in time to the June 3, 2019 bid deadline. The American Academy of Actuaries recently raised similar concerns created by the timing of the Proposed Rule and the potential negative consequences that could result in the Part D program, including higher administrative burden for plans and implications for 2020 benefit designs and premiums.\(^\text{34}\) An actuarially sound bid requires plans to be able to project drug costs—including anticipated rebate amounts. The Final Notice and Call Letter for 2020, which were released April 1, 2019, were incomplete and without instructions regarding how plans should determine such costs in light of fundamental questions such as whether the rule will in fact be implemented for 2020, whether or how it may be modified, and how stakeholders including manufacturers will respond to the changes.

We also have been concerned that a 2020 effective date would force Part D plans to alter their bids to accommodate the Proposed Rule even before (and regardless of whether) it is formally promulgated as a final rule. This would essentially render the opportunity to comment meaningless, since solicited comments would be considered only after the proposal itself would have already changed how Part D plans submit bids for 2020.

These uncertainties would create a Hobson’s choice for participating plans. Plans that submit bids in accordance with current regulations would be subject to serious risks, which include exposure to substantial losses, if HHS in fact decides to finalize the proposal and net drug costs are much higher.

than anticipated. On the other hand, plans that project drug costs would increase under the new and untested structure – as OACT itself projects – could face competitive issues, particularly if HHS ultimately decides to postpone the effective date of the rule or make substantial changes. These types of fundamental uncertainties are inconsistent with the design of Part D.

As noted above, CMS issued a memorandum on April 5, 2019 that directed plan sponsors to “submit bids for CY2020 in a form and manner that is consistent with the Anti-Kickback Statute law and regulations in effect as of the bid submission deadline, including for the purposes of bid development, the treatment of manufacturer rebates per our existing rules and guidance related to Direct and Indirect Remuneration.” The memorandum also announced that if there is a change in the safe harbor rule for 2020, CMS would conduct a voluntary, two-year demonstration that would change Part D risk corridors.

We appreciate CMS’ instruction on how to submit bids for 2020, and for announcing a potential mechanism that could limit exposure to potential substantial losses and presumably limit the potential for substantial beneficiary premium increases for 2020 and possibly 2021. However, we urge CMS to provide substantially more detail as soon as possible to eliminate any uncertainty and allow stakeholders to adequately assess whether these steps would be effective in the short term. Moreover, even if the guidance will adequately address the immediate premium and bidding impacts of the Proposed Rule, it will not alleviate other fundamental concerns described at length in this comment letter. They include higher premiums after the demonstration ends for most enrollees who would see little or no benefit from the proposed changes; greater government costs (which may be even higher under the demonstration); and a shifting of funds to drug makers. In addition, if the Proposed Rule were to be implemented with a 2020 effective date, we would still have concerns about the likelihood of significant operational challenges associated with moving to a new system with little time to rigorously test the system, especially given the potential application of both criminal and civil/administrative penalties under the Anti-Kickback Statute.

B. Legal Barriers

1. Proposed Rule Fails to Address Serious Antitrust Law Questions Under a Chargeback System

AHIP is very concerned that the proposal does not address serious questions that have been raised about whether the chargeback structure HHS envisions is consistent with provisions of the Robinson-Patman Act. Unless these questions are clearly addressed, we believe they pose a serious barrier to successful implementation of the structure as proposed.

A recent legal analysis by the law firm Foley Hoag stated that: “As currently worded, the Robinson-Patman Act is potentially implicated where a seller offers differential discounts or rebates to

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35 In addition, the Proposed Rule would impermissibly operate retroactively as applied to these bids, providing such plans with no time to renegotiate with drug makers and pharmacies, take all the other necessary operational steps to implement the rule, and potentially obtain negotiated discounts for their enrollees.
competing purchasers.” The analysis closely examined the law in the context of a 1994 lawsuit brought by a group of pharmacies that challenged discounting practices by drug manufacturers. It noted that retrospective rebating with PBMs based on market share became commonplace “as a way to allow manufacturers to differentially price their products without violating applicable antitrust laws.”

Ultimately, the analysis finds: “Absent Congressional action, manufacturers would likely be unwilling or unable to offer the same level of price concessions through an upfront discounting system (as suggested in the Proposed Rule) that they do currently by way of market share-based rebates. FDA Commissioner Scott Gottlieb and others have recognized the importance of legislative change to ensure manufacturers will provide upfront discounts.”

Given these concerns, if HHS were to move forward with a proposal that shifts away from the existing rebate structure, it should not do so without enactment of legislation to address these Robinson-Patman Act concerns. Otherwise, there would be significant uncertainty about the degree to which discounts would be available under the new structure.

2. Proposed Rule’s Ban on Rebates Is Inconsistent with the Non-Interference Clause

Under §1860D-11(i) of the Social Security Act (SSA), “the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors.” This section, which has come to be known as the non-interference clause, is a critical element of the Part D program’s design. The language of the statute indicates the goal of the non-interference clause is to promote competition by prohibiting interference with negotiations between stakeholders. As part of such negotiations, Congress specifically intended for Part D plans “to negotiate price concessions directly with manufacturers.” The statute indicates that in some circumstances, “rebates” would be a component of the “negotiated prices” that resulted from such negotiations.

In 2014, CMS confirmed the agency’s understanding that the non-interference clause barred policies that would interfere with negotiations for rebates. In an extensive discussion of the agency’s interpretation of the non-interference clause, CMS stated:


37 Ibid.


39 See SSA § 1860D-2(d)(1).
We believe the intent of 1860D-11(i) is to ensure that we do not create any policies or become a participant in any discussions that could be expected to interfere with negotiations leading to the selection of drug products to be covered under Part D formularies. By this we mean selection by Part D sponsors (or other intermediary contracting organizations) of specific manufacturers’ products for inclusion on formularies, formulary tier placement, and negotiations of acquisition costs, rebates, and any other price concessions. We believe this interpretation is consistent with a textual reading of 1860D-11(i) and with how private market transactions determine which prescription drug products are covered under Part D plans.40

CMS further explained how government policies could inappropriately influence competitive decisions. For example, CMS states that “government involvement could affect market forces around prescription drugs in ways that change the value that would otherwise be assigned to these products in a competitive market.” CMS pointed out that value, in the case of multiple source or therapeutically equivalent brand drug products, is “determined by comparing both the list prices of the drug products and the level of rebates negotiated between the sponsor and the manufacturers of the brand products.”41

In interpreting the non-interference clause to bar policies that would interfere with rebate negotiations, CMS recognized that (i) the non-interference clause was designed to prevent the government from picking winners and losers in formulary decisions by affecting the value of the products, and (ii) the value of products is a function of both list prices and rebates.

By precluding negotiations regarding rebates, the Proposed Rule would plainly interfere with negotiations between Part D plans and drug makers regarding prices. This is precisely the sort of interference with competition that CMS has already recognized the non-interference clause was designed to prevent. Indeed, changing market forces affecting coverage decisions is an expressed goal of the Proposed Rule. The non-interference clause prohibits both the means (direct interference with price negotiations by prohibiting one form of price concession) and the end (changing the competitive dynamics governing drug values). As the statutory prohibition under 1860D-11(i) applies to “the Secretary” of HHS, and therefore just as strongly to anti-kickback regulations proposed by OIG as to Part D regulations issued by CMS (as reflected by the Proposed Rule’s statement that “the Department of Health and Human Services”—not OIG—proposes the amendment). Any guidance from components within HHS jurisdiction, including the OIG, must comply with the non-interference rule.

Despite the applicability of the non-interference clause to the Proposed Rule, as well as the Proposed Rule’s substantial departure from the Department’s prior interpretation of the clause, HHS does not address the issue in its initial proposal. We believe the Administrative Procedures Act requires the


41 Ibid.
Department to provide an analysis of this issue. Further, as a fundamental policy matter, we have serious concerns that finalizing the proposal would establish a dangerous precedent for future regulatory actions that could further undermine the integrity of Part D. At its core, the Part D program relies on competition and private sector negotiation to deliver high quality, cost effective coverage. As noted in the recommendation section below, if HHS intends to pursue a proposal that would so fundamentally alter the way manufacturers and Part D plans negotiate coverage of drugs under Part D, it should be part of a legislative package that ensures the core principles of non-interference are preserved for any future administrative actions.

3. Part D Statute Expressly Approves Use of Drug Rebates

Viewed as a whole, the statute governing the Part D program expressly contemplates and approves of direct rebates between drug manufacturers and Part D plans. For example, several parts of the SSA include instructions about how to account for rebates:

- Section 1860D-2(d)(1) includes rebates in the definition of negotiated price under some circumstances, and (d)(2) requires reporting of rebates.
- Section 1860D-15(b) excludes rebates from the amounts taken into account in calculating the government’s reinsurance payment.
- Language referring to rebates, similar to that in the reinsurance section, can be found in the risk corridor provisions of Part D, at 1860D-15(e)(1)(B).

The MMA, which created the Part D program, was enacted decades after the anti-kickback statute, which was originally enacted as part of the Social Security Amendments of 1972. Moreover, Congress had already amended the anti-kickback statute to exempt discounts (see 42 U.S.C. § 1320a-7(b)(3)(A)) and the Department had expressly interpreted discounts to include rebates (in 1991, in adopting the safe harbor it now proposes to amend). On their face and viewed in historical context, the Part D provisions discussed above reflect congressional intent to permit rebates from drug manufacturers to plans under Part D. If there were a conflict between the Part D statute and the anti-kickback statute on this point, Part D’s approval of rebates would control both because it is more specific and because it was later-enacted. But the statutes can easily be read harmoniously because the anti-kickback statute expressly contemplates rebates like those Congress approved for Part D, and

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44 Bulova Watch Co. v. United States, 365 U.S. 753, 758 (1961) (“[A] specific statute controls over a general one without regard to priority of enactment.”); International Union Local 737 v. Auto Glass Employees Credit Union, 72 F.3d 1243, 1248–49 (6th Cir.1996), quoting Boudette v. Barnette, 923 F.2d 754, 757 (9th Cir.1991) (“When two statutes conflict[,] the general rule is that the statute last in time prevails as the most recent expression of the legislature's will.”).
exempts any “discount” that is “properly disclosed and appropriately reflected.” Only the Proposed Rule conflicts with this congressionally harmonized statutory regime.

Additionally, a statute should be construed so that effect is given to all its provisions and no part will be inoperative or superfluous, void or insignificant. If the anti-kickback statute were read in a way that prohibited rebates under Part D, it would render the rebate provisions referenced above in Part D superfluous.

Given that our reading of the clear legislative language is in accord with these long-accepted principles of statutory construction, issuing the Proposed Rule would conflict with Congress’ clearly stated intent that competitively negotiated rebates be unconstrained by regulatory interference in the Part D bidding process. The Proposed Rule would thus receive no deference if it were issued as proposed. If HHS wishes to move forward with an approach that eliminates congressionally-permitted rebates, it would require legislation to do so.

C. Ability to Negotiate Discounts Is Diminished

Under the current system of retrospective rebates, plans can negotiate discounts from drug makers by applying a range of clinical management tools including formulary design and utilization management. Drug makers, in turn, offer higher rebates to plans that will increase the volume of their products through more favorable formulary placement and fewer utilization controls. Using the clinical management tools currently allowed under Part D, the Medicare Trustees report that Part D plans and PBMs negotiated an average manufacturer rebate of 19.9 percent in 2016, which is estimated to increase to 28.1 percent by 2028. The effect of new clinical management tools introduced by CMS last year, such as indication-based formularies, or those anticipated at the beginning of 2020, such as step therapy for drugs in the six protected classes, will further increase plan leverage to negotiate higher rebates in Part D.

We are concerned that eliminating retrospective rebates would restrict certain negotiation tools and thereby limit the amount of discounts obtained from drug makers. For instance, while the Proposed Rule is not entirely clear on this point, the OACT analysis states that: “because many of the current rebate arrangements are contingent on measures such as market share that would not be possible in the chargeback system, there is less assurance that the chargeback would provide the return on investment required by manufacturers.” In other words, the Proposed Rule appears to limit negotiating tools that have been used effectively by plans and PBMs to lower drug costs, which may shift more of the negotiating leverage towards drug makers. As discussed below, we are also concerned that these proposed changes would prevent, or create major barriers to the negotiation of,

46 Clark v. Rameker, 573 U.S. 122, 131 (2014) (A “statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous.”).
48 See footnote 6.
value-based arrangements between drug makers and plans as they would not be able to negotiate for retrospective payment for drugs based on real-life patient outcomes.\textsuperscript{49}

We also have serious concerns that these proposed changes would give drug makers the ability to reverse-engineer discounts offered by other drug makers competing for market share. This behavior would prevent good faith negotiations with plans and increase costs for public programs. These impacts are well understood.

- The Federal Trade Commission (FTC) and other economists have raised concerns about the anticompetitive effect of competing firms 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.”\textsuperscript{50}
- Congressional testimony indicates similar conclusions from antitrust authorities in other countries – that more transparent contracted prices tend to lead to higher prices.\textsuperscript{51}
- CBO has stated 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.”\textsuperscript{52}

D. Key Elements of the Proposed Rule Are Vague and Ambiguous

It is critical that stakeholders understand precisely what is permitted and required under the new chargeback structure. HHS states the violation of the anti-kickback statute would be considered a felony “punishable by fines of up to $100,000 and imprisonment for up to 10 years” and “may also result in the imposition of civil monetary penalties.”\textsuperscript{53}

We have very serious concerns that there is widespread confusion and uncertainty about key elements of the Proposed Rule. These ambiguities would significantly complicate the contracting, negotiation, and implementation processes for various stakeholders and create even more barriers to

\textsuperscript{51} 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/.
\textsuperscript{53} 84 Fed. Reg. 25 (February 6, 2019), p. 2345.
successful implementation of the proposed changes. Examples of elements requiring substantially more clarity are provided below.

1. Status of Value-Based Arrangements Is Unclear

HHS states that it “does not intend for this proposal to have any effect on existing protections for value-based arrangements between manufacturers and plan sponsors.” Yet the proposal appears to foreclose discounts that would retrospectively measure and pay for drugs based on patient outcomes. If the Proposed Rule would prevent a discount from being paid based on outcomes measuring a drug’s efficacy, it could severely restrict the use of value-based arrangements. Without clarity, the Proposed Rule could substantially frustrate the Administration’s goal of expanding the use of value-based arrangements. Moreover, even if such arrangements would be permissible, we have serious concerns that drug makers would be less willing to offer large discounts once competitors are able to determine each other’s negotiated discount amounts.

2. Proposed Rule Includes Numerous Questions About Permissible Structure of Chargeback Arrangements

The proposal defines chargebacks as payments made “directly or indirectly” by a drug manufacturer to a pharmacy. In addition, it requires that any reduction in price must be “completely applied” to “the price charged to the beneficiary at the point of sale.” However, there are many questions about what entities and types of arrangements will satisfy these standards.

For example, the preamble seems to suggest that plans and PBMs are not expected to have a role in the chargeback payment structure. Yet the proposed regulatory language itself does not foreclose such a role. Clarity on this point would be critical if HHS were to move forward with the rule, given that plans and PBMs may be in the best position to coordinate and effectuate the flow of discounts (especially within short timelines). Moreover, the proposed regulatory language fails to clarify a number of key issues, including how plans should “completely apply” discounts and what the price charged “to the beneficiary” would be under the proposed structure.

These questions are magnified in the Medicaid program, where the state is an additional active stakeholder in the process involving supplemental rebates. Without very clear guidance aided by detailed examples of permissible and impermissible arrangements involving supplemental rebates, there likely would be differing interpretations across states and even greater levels of confusion than in Part D.

We believe the proposed changes in the safe harbor could not be finalized without significant clarifications of all issues. The threat of criminal liability alone should compel HHS to eliminate ambiguities so stakeholders can understand exactly how the proposed system would work within various payment structures in Part D and in Medicaid. Moreover, these clarifications are so core to the underlying proposal that if HHS wanted to move forward with the proposal, it should re-propose

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54 See footnote 49.
the rule as clarified to ensure stakeholders have a sufficient understanding of the proposal to enable them to review and make meaningful comments.

E. No Mechanism to Limit Cost Increases

AHIP strongly disagrees with the assumption that drug makers will lower list prices in response to the Proposed Rule. We believe that the Proposed Rule and the OACT analysis fail to provide reasonable rationale, historical data, or other evidence for their assertion that drug makers will respond to the Proposed Rule by lowering list prices and by increasing list prices at a lower trend. Instead, the new chargeback structure could result in significantly higher net costs, and therefore significantly larger premiums and increased government spending.

1. No Guarantee of Lower List Prices

OACT estimates that drug makers would use a portion of the amounts currently paid as rebates to reduce list prices. Specifically, OACT assumes that brand drug list prices would decrease approximately 3.2 percent, and those impacts would apply across the entire U.S. market since list prices do not vary between Medicare and the private sector.

We find this assumption to be highly questionable. Drug makers have repeatedly disregarded decades of pleas and pressure from several Administrations and Congresses to reduce prices. Most recently, drug makers rebuked the Administration by substantially raising prices since the release of the Blueprint.55 Testimony by drug industry CEOs at a recent Senate hearing, where they pointedly refused to make any promises relating to drug pricing, further confirms they do not intend to lower list prices as a result of the Proposed Rule.56 Accordingly, OACT’s assumption that drug makers would lower prices in a chargeback process, in part, to “alleviate public pressure on high drug prices” is extremely puzzling. The reality is public pressure has never restrained drug maker practices, particularly over a sustained period, and it is unlikely to do so now.

2. Drug Makers Likely Would Reduce Discounts and Raise Net Costs

OACT assumes 15 percent of existing manufacturer rebates for Medicare Part D and Medicaid supplemental rebates would be retained by drug makers. Specifically, OACT notes:

After considering several issues, we established an assumption for the level of rebates that would be retained by manufacturers. First, because many of the current rebate arrangements are contingent on measures such as market share that would not be possible in the chargeback system, there is less assurance that the chargeback would provide the return on investment required by manufacturers. Secondly, as rebates have evolved over many years in the current

55 See footnotes 18-20.

system, manufacturers have increased rebate levels to compete for certain drugs that vary across payers. The change to the chargeback system would create an opportunity to lower the level of rebates currently provided. Lastly, given the relatively low recent price trend growth and policies that have required additional manufacturer concessions, this proposal would give manufacturers an opportunity to recapture some of these forgone revenue streams such as those that occurred from the changes in the Coverage Gap Discount Program included in the BBA. Based on these factors, we assumed that 15 percent of the existing manufacturer rebates for Medicare Part D and Medicaid supplemental rebates would be retained by drug manufacturers.

We agree with OACT that drug makers will likely use the transition to a new system as an opportunity to increase their revenue and profits. Given their strong opposition to the change in the coverage gap discount program enacted under the BBA, we also think it is reasonable to assume they will use this as an opportunity to essentially undo that change and frustrate Congressional intent. The implementation barriers noted above would likely work to further reduce the discounts drug makers are willing to give.

Where we differ with OACT is in thinking that drug makers would limit their potential revenue gain to 15 percent of discounts. Drug makers have repeatedly shown that no level of public pressure will stop them from increasing their own revenues, shifting costs onto others, and raising profits whenever possible. They have demonstrated no concern about increasing Part D drug costs, increasing premiums for seniors, or putting greater burdens on taxpayers. Accordingly, we believe drug makers will use the transition to a new system as an opportunity to maximize revenue while minimizing their discount obligations.

3. Overall Impacts: Higher Premiums and Government Spending

The clear winner under this Proposed Rule would be drug makers. Within Part D alone, OACT estimates that drug makers’ liability for coverage gap discounts will be reduced by $40 billion over 10 years. More broadly, OACT estimates that national expenditures for prescription drugs will increase by $137 billion. Most of this increased spending will likely represent additional drug maker revenue.

The clear losers under this Proposed Rule would be most seniors and people with disabilities on Medicare, state Medicaid programs, and taxpayers. OACT estimates that lower discounts and other impacts will translate into a 25 percent increase in Part D premiums over the next 10 years, with 19 percent of the increase occurring in the first year. Combined state and federal costs under Medicaid would increase by almost $2 billion as well.

However, the actual negative impacts from this Proposed Rule may be much larger than what OACT has estimated because drug makers could keep more than 15 percent of current rebate dollars as additional revenue. As such, AHIP commissioned Avalere Health to replicate, as closely as possible, OACT’s methodology in its analysis of the Proposed Rule and use those assumptions to model the impacts on premiums and government costs if drug makers keep a larger portion of current rebate
dollars, namely 30 and 50 percent, in response to the rule. The results of the analysis are provided in the table below.

**Stakeholder Impact of Eliminating Rebates Under Alternative Scenarios, Includes Induced Demand, 2020-2029 (in billions)**

<table>
<thead>
<tr>
<th>Share of Rebates Retained by Manufacturer</th>
<th>OACT Estimates</th>
<th>Projections Based on OACT Estimates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15%</td>
<td>30%</td>
</tr>
<tr>
<td>Beneficiary Costs</td>
<td>-$25.2</td>
<td>$1.0</td>
</tr>
<tr>
<td>Cost Sharing</td>
<td>-$83.2</td>
<td>-$69.6</td>
</tr>
<tr>
<td>Premium</td>
<td>$58.0</td>
<td>$70.5</td>
</tr>
<tr>
<td>Government Costs</td>
<td>$196.1</td>
<td>$291.6</td>
</tr>
<tr>
<td>Direct Subsidy</td>
<td>$258.7</td>
<td>$271.3</td>
</tr>
<tr>
<td>Reinsurance</td>
<td>-$20.3</td>
<td>$50.0</td>
</tr>
<tr>
<td>Low-Income Cost Sharing Subsidy</td>
<td>-$57.7</td>
<td>-$48.5</td>
</tr>
<tr>
<td>Low-Income Premium Subsidy</td>
<td>$15.4</td>
<td>$18.9</td>
</tr>
<tr>
<td>Manufacturer Gap Discounts</td>
<td>-$39.8</td>
<td>-$33.2</td>
</tr>
</tbody>
</table>

According to the analysis, if drug makers retained 50 percent of current rebates:

- **Government spending** would increase more than twice as much as OACT estimated, or nearly half a trillion dollars over a 10-year period — **$410 billion**.
- **Beneficiary premiums** would increase an estimated **$85.7 billion**, or nearly 40 percent.
- **Net out-of-pocket spending** would increase by **$36.5 billion** ($85 billion in higher premiums offset by $49.2 billion in lower cost-sharing).
- Even based on the assumption that drug makers only retain 30 percent of current rebate dollars, government spending would increase by $291.6 billion, beneficiary premiums would increase by $70.5 billion, and net out-of-pocket spending would still increase by $1 billion.

We note this effort by HHS to improve the Part D program could in fact cost nearly as much as the CBO estimated that creating the entire Medicare Part D program would cost. In addition, out-of-pocket spending would increase by $1 trillion over a 10-year period.

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57 For their analysis, Avalere was asked to develop a baseline estimate of Part D spending from 2020 to 2029, and then develop three alternative scenarios: 1) drug makers retain 15 percent of rebates, 2) drug makers retain 30 percent of rebates and 3) drug makers retain 50 percent of rebates. Under all three scenarios, the portion of the rebate not retained by the drug makers would be applied to prices at the point of sale, either through a price reduction or through a chargeback. Avalere also modeled the impact of induced demand from lower prices under all three scenarios.


59 Ibid.

pocket spending, on average, could actually increase for seniors, which would run counter to HHS’ goal of lowering out-of-pocket costs.

Simply stated, the potential negative impacts from HHS’ proposal present grave challenges to the more than decades-long effort by Part D plans and their contracted PBMs, working in partnership with the government, to deliver high quality, affordable drug coverage to seniors and people with disabilities. According to MedPAC, 90 percent of Medicare beneficiaries now have access to a zero-premium MA plan that includes Part D coverage\(^{61}\) (MA-PD plan) – if Part D premiums increase by 40 percent, access to zero-premium MA-PD plans could be substantially reduced. For those MA-PD plans that do not increase premiums, the costs will likely be absorbed through increases in cost-sharing for medical services or reductions in supplemental benefits such as dental, vision, hearing, or the new flexible supplemental benefits that will become available in 2020 under the BBA. The cost estimates reinforce that HHS absolutely cannot move forward with the Proposed Rule given its serious defects and impacts.

We also note that the CMS guidance memorandum issued on April 5, 2019 may have a short-term impact on premiums by directing Part D sponsors to submit bids for 2020 consistent with rebate rules in effect as of the bid submission deadline. Because of the late release of the guidance we were unable to meaningfully assess the potential impacts in this comment. However, it seems likely that any premium impacts would be temporary. Moreover, the guidance could cause government spending to be even higher than estimated and drug makers would remain the clear winners as the guidance would not do anything to reduce expenditures for drugs.

F. Proposed Changes to Medicaid Would Harm Medicaid Enrollees

1. Medicaid MCOs Offer Tremendous Value

Medicaid MCOs provide states with a critically important tool for controlling high drug costs. For example, based on all Medicaid-paid prescriptions dispensed in 2017, over 70 percent of the nation’s Medicaid prescriptions were paid by MCOs at an average net (post-rebate) cost of $37. The MCOs’ cost was 26 percent below the average cost in the fee-for-service (FFS) setting ($50). A key driver in these savings is steering volume to generics when a generic alternative is available – in the Medicaid MCO setting the use of generics (as a percentage of all prescriptions) is almost 5 percentage points above FFS.\(^{62}\)

2. Proposed Rule Would Not Benefit Medicaid Enrollees

Despite this clear value, the Proposed Rule would introduce significant costs and uncertainties for states using Medicaid MCOs without any clear benefit. HHS acknowledges that the Proposed Rule would not generate savings for Medicaid enrollees who already have little or no cost sharing. Thus, a

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core objective in proposing the rule for Part D – to lower costs for certain enrollees – is irrelevant in Medicaid.

3. Proposed Rule Would Have Negative Operational and Cost Impacts

The proposal would introduce operational challenges and complexities, raising pharmacy costs that would flow through to Medicaid programs. We are concerned that these operational challenges could negatively impact Medicaid enrollees’ access to drugs at the pharmacies of their choice.

As discussed elsewhere, we also are concerned drug makers will use the transition to a new structure as an opportunity to reduce the level of discounts they would otherwise be willing to pay. OACT acknowledges this outcome is likely, but we believe the impact will be greater than what OACT estimates.

OACT also assumes the Proposed Rule would lead to lower list prices. However, they acknowledge those savings, if they were to materialize (which we highly doubt), would be offset by reductions in Medicaid mandated rebates. The net effect, according to OACT, would be higher costs for federal and state governments of roughly $2 billion. Given the concerns noted above, we believe the negative impacts could be significantly greater. The additional costs could severely strain limited state Medicaid budgets and/or inhibit the ability of Medicaid MCOs to deliver comprehensive drug benefits.

4. Proposed Rule Creates Unlevel Playing Field That Could Promote Less Effective Approaches

As discussed above, there are numerous questions about how the Proposed Rule is expected to work, both generally and specifically in the Medicaid context. These ambiguities could create a chilling effect on state and MCO abilities to negotiate discounts from drug companies. The ambiguities could even have an impact on state decisions involving the use of MCOs.

In addition, the rule only prescribes supplemental rebates paid to Medicaid MCOs and PBMs, and not supplemental rebates paid to states. According to HHS: “This proposed rule recognizes that rebates paid by manufacturers to Medicaid MCOs should be treated differently than supplemental rebates paid by manufacturers to states because of the differing risk posed under the Federal anti-kickback statute.” However, as a practical matter we believe the risks are not different. Under current law, states determine how supplemental benefits are negotiated and paid by virtue of their ability to contract with Medicaid MCOs. If, as HHS acknowledges, the risks under the anti-kickback law do not warrant new restrictions on payment of supplemental rebates to states, such new restrictions should also not be warranted for rebates paid to plans, since the states essentially endorse such payments through their contract arrangements. The distinction between payments to states and payments to plans therefore is arbitrary and inappropriate.

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In the end, the Proposed Rule would simply penalize states that rely on comprehensive drug benefit arrangements with Medicaid MCOs as the most cost-effective choice for delivering Medicaid benefits. It could require that the states adopt more costly or complex alternative arrangements, further increasing federal and state health care program costs more than OACT estimates.

IV. RECOMMENDATIONS

As demonstrated by the data and evidence in this comment, the focus on rebates is a distraction. Drug costs are high because of pricing decisions made by drug makers, which are entirely within their control. The biggest driver of costs are drugs with no real competition that rarely offer rebates. Even focusing just on rebates, the Proposed Rule would be far worse than the existing system. It would simply strengthen drug makers’ ability to control the prices they set, weaken negotiating leverage for plans and PBMs to obtain lower prices, and raise costs for patients, consumers, and taxpayers in 2020 and beyond as it shifts funds to drug makers. Additionally, since Medicaid enrollees already face little or no co-payments for their drugs, the proposal will impose unfair and unnecessary costs for states using Medicaid managed care plans.

However, AHIP acknowledges there are legitimate concerns regarding the complexity of the current drug discounting system. Health insurance providers are not committed to rebates. They are committed to getting the lowest drug costs for patients, consumers, and taxpayers. Accordingly, AHIP urges HHS to withdraw the Proposed Rule. At the same time, AHIP and our members are prepared to partner with HHS to consider a set of workable alternatives to the rebate structure that would accomplish the goals of reducing drug prices and lowering costs for patients and consumers.

If HHS wants to further pursue alternatives to rebates, it should consider a package of bigger and bolder legislative and regulatory solutions that will ensure meaningful, market-wide, and sustainable improvements. Alternatively, if the Administration insists on moving forward with a limited regulatory approach, we urge HHS to withdraw the Proposed Rule and instead consider several changes to the existing system that would meaningfully promote HHS’ goals; avoid shifting money from patients, consumers, and taxpayers to drug makers; and limit harm to states using Medicaid managed care. Our specific recommendations are described below.

A. Bigger and Bolder Solutions

A workable alternative to a rebate structure must include several components.

1. Preserve and Expand Private Sector Negotiation

Regardless of any changes that might be made with respect to rebates or other discounts, it is crucial that plans and their contracted PBMs have the ability to expand private-sector leverage to deliver greater competition, choice, and the lowest possible costs for patients and consumers. We appreciate that the Administration has repeatedly recognized the importance of this private sector role in our health care system through its statements and its proposals (e.g., giving more negotiating flexibility
to Part D plans for certain classes of drugs while ensuring continued patient access to the drugs they need. Where there is competition among drugs, plans need to be able to exercise a full complement of negotiating tools on behalf of their customers – individuals, states, employers, and others.

2. Address Legal Barriers

Legal barriers to implementation of an effective alternative to the rebate system must be removed. This includes addressing the long-standing antitrust concerns that were a major contributor to the development of the rebate system. Beyond removing legal barriers, the non-interference clause must be protected from future government attempts to circumvent the private sector negotiating structure that is at the heart of the Part D program. In addition, conforming changes would be needed to rebate language in the Part D provisions of the SSA. We believe these barriers would need to be addressed through legislation.

3. Restrain Drug Costs

Drug makers should not have an opportunity to take advantage of a transition to an alternative system by increasing the net costs of their drugs and shifting more money to seniors paying premiums and taxpayers financing federal and state government spending. Accordingly, any workable alternative to the rebate system must ensure drug costs do not rise during the transition. This result could be achieved through a maintenance of effort requirement or other similar obligations. It would also require meaningful CMS oversight of the drug makers and other entities that may play a new role in the alternative structure, along with other protections (e.g., reporting and appeal rights). These steps would ensure the system operates as intended, significant new barriers to drugs do not develop, and plans and their vendors are held harmless for actions by these other entities. We believe several regulatory steps referenced below could be options. However, we recommend that legislative provisions be explored to ensure patients, consumers, and taxpayers are protected.

4. Provide an Appropriate Transition Period

Given all the operational and other challenges discussed above concerning a change to an alternative discounting system, the effective date of any such alternative should be no earlier than 2022. Any new approach, particularly one requiring the development and testing of costly new systems and capabilities, resource-intensive changes to a multitude of contracts, and a range of other operational steps, must have an appropriate transition period.

5. Address the Underlying Problem of High Drug Prices

We believe that any changes involving rebates should be part of a broader package designed to solve the root causes of high drug prices: the fundamental lack of market competition and gaming of the
system by manufacturers to block patient and consumer choice. Such comprehensive efforts could include the following:

a. **Reduce gaming by manufacturers limiting entry of new generic and biosimilar competitors**

AHIP strongly supports the “Creating and Restoring Equal Access to Equivalent Samples (CREASES) Act.” This bipartisan bill offers common sense reforms that would discourage brand name drug manufacturers from blocking the availability of generic drugs by abusing Risk Evaluation and Mitigation Strategies (REMS) that are otherwise required by the Food and Drug Administration (FDA) to promote patient safety.

b. **Ensure federal rules promote the availability of interchangeable biosimilars**

AHIP supports key provisions of the FDA’s Biosimilars Action Plan and recommends that HHS finalize FDA guidance related to interchangeability, make the development and approval of biosimilars more efficient, and develop effective communication tools and resources for providers and patients on the safety and efficacy of biosimilars.

c. **Provide more transparency and timely information about drug and biologic patents to promote greater generic drug and biosimilar competition**

AHIP believes that manufacturer gaming of patents has led to lower amounts of and less meaningful market competition. For example, although Humira was introduced to the market in 2002, it is still the top selling drug in America even after 17 years due to a lack of meaningful competitors, which is directly caused by AbbVie’s large patent estate for Humira.64 AHIP recommends that the HHS work closely with Congress to answer the recent call for pharmaceutical patent reform.

d. **Revise market exclusivity periods (e.g., biologics) and orphan drug incentives**

AHIP supports legislation to reduce the exclusivity period for brand name biologics and enhanced oversight of “pay-for-delay” arrangements that prevent generics and biosimilars from coming to market. We also support legislative efforts to reexamine the incentives offered for drug makers pursuing orphan drug status.

e. **Require drug makers to publish true research and development (R&D) costs and explain price setting and price increases**

Drug makers’ ability to set and increase prices without justification is the core problem of the nation’s inability to afford prescription drugs. Though drug makers typically point to innovation when trying to justify high prices, they never actually produce real data. Drug makers should be held to accountability and transparency oversight and standards by publishing the true R&D costs for their products as well as justifying to HHS and the public the reason for setting high list prices and constantly increasing them unreasonably.

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f. Disclose list prices in direct-to-consumer (DTC) advertisements
AHIP recommends that CMS finalize its proposal to list prices in certain DTC advertisements. In fact, we recommend that HHS take a bolder and broader step towards regulating DTC advertisements of all media (e.g. print, television, online, merchandise).

g. Inform patients and physicians on effectiveness and value
AHIP supports efforts by HHS, the Institute for Clinical and Economic Review, and certain other stakeholders to educate and inform both patients and physicians on paying for drugs based on their effectiveness and value. We believe that payment arrangements based on a drug’s effectiveness and value is one potent way to limit costs and spending and that patients and providers should be engaged.

h. Address barriers to value-based pricing
Though value-based arrangements could be a helpful mechanism to pay for certain high cost drugs, numerous barriers remain to their full adoption. AHIP recommends that HHS help deliver a pathway towards robust use of value-based arrangements, either through demonstrations, waivers, regulatory changes, or legislation. We also recommend that HHS work with AHIP and Congress to establish an independent assessor of value for high cost drugs.

i. Exercise HHS authority to introduce market competition when manufacturers fail to engage in reasonable, good-faith negotiations with payers
Given drug makers’ egregious pattern of behavior of setting high prices and increasing them without justification, we believe HHS should seriously consider using its existing authority (e.g., under 28 U.S.C. section 1498) to introduce market competition that will better ensure negotiation takes place. In fact, we believe that simply the possibility of HHS exercising its authority could have beneficial impacts on the market.

B. Medicaid

1. HHS Should Exclude Medicaid MCOs from the Proposed Rule
As stated above, AHIP strongly objects to HHS’ proposal to subject supplemental rebates negotiated by Medicaid MCOs to the restrictions of the new anti-kickback safe harbor. It would provide no benefits to Medicaid enrollees. At the same time, it would introduce new operational challenges, costs, and uncertainties into the Medicaid programs of many states currently using Medicaid MCOs and potentially strain state budgets. We also note the state’s ability to control the contracting process with Medicaid MCOs, so if there is minimal anti-kickback risk for supplemental rebates paid to states, there should similarly be minimal risk for rebates paid to MCOs. Regardless of what HHS
decides to implement in a final rule with respect to Part D, we urge HHS to exclude Medicaid MCOs from any new restriction on the use of supplemental rebates.

2. Alternative Medicaid Approaches that Maintain Use of Managed Care in Medicaid

Despite the concerns noted above, if HHS chooses to move forward with a new safe harbor that restricts the use of supplemental rebates in Medicaid MCOs, it is critical that HHS ensure parity between various Medicaid options relating to drug benefits. States should be able to choose the approach that best meets their needs without federal rules that unnecessarily affect the relative values of different approaches. Accordingly, HHS should apply any restriction on supplemental rebates equally to rebates paid to Medicaid MCOs and those paid to states. As noted above, we believe the relative risks to federal health care programs are essentially the same under either scenario.

As an alternative, HHS could, instead of working within the safe harbor, give states the flexibility on whether to implement a point-of-sale model or to keep the existing system for its Medicaid MCOs. This would give states and various affected stakeholders the opportunity to determine the most effective approach to managing drug costs for their own region. It might also create evidence about the effectiveness of different approaches that could inform potential future policymaking in this area.

C. Part D Recommendations Within the Existing System

As demonstrated above, the Proposed Rule will make the drug affordability problem in this country worse, not better. If HHS continues to believe an alternative to the rebate system is necessary, the only effective approach would be to pursue the change as part of a bigger and bolder strategy involving a package of legislative and regulatory steps, such as those outlined in this comment letter. If HHS is not prepared to pursue a bold approach, then AHIP urges HHS to withdraw the Proposed Rule. If HHS then wants to pursue changes within the existing rebate system, they should be done in a far more targeted way. We believe there are changes HHS could consider that would achieve key HHS goals without creating a new, complex, expensive, and untested structure that would mainly benefit drug makers at the expense of most seniors and taxpayers.

One approach would involve targeting reductions in out-of-pocket costs to Part D enrollees taking drugs with high costs and significant rebates. Another would prohibit certain specific types of rebate agreements, to address HHS concerns about arrangements that are perceived as incentivizing higher cost drugs. The third recommendation would impose regulatory mechanisms to restrain drug price increases. However, these changes could not be applied for 2020. If HHS is willing to consider them, we recommend proposing the changes in a new rulemaking process and ensuring it includes an adequate transition period, so they can be implemented successfully.

1. Lower Out-of-Pocket Spending for Certain High Cost Drugs

Part D plans are permitted to place drugs on a “specialty” tier if their negotiated prices exceed the dollar-per-month amount established by CMS in the annual Call Letter (the current threshold is $670 per month). Cost-sharing associated with the specialty tier is limited to 25 percent after the standard
deductible and before the initial coverage limit, or up to 33 percent for Part D plans with decreased or no deductible under alternative prescription drug coverage designs.

A recent CBO report analyzed Part D drugs similar to those on the specialty tier (i.e., those costing at least $6,000 per year in 2015). Looking at the 50 top-selling drugs in this category, CBO found they had an average retail price per prescription of $4,380. Average out-of-pocket costs for these drugs increased from $1,750 in 2010 to $3,540 in 2015, as net spending (which AHIP notes was attributable to price increases) increased fourfold — from $8,970 in 2010 to $36,730 in 2015. In fact, according to MedPAC’s March 2019 Report to Congress, over 360,000 Medicare enrollees in 2016 filled a prescription with a price so high that a single claim pushed them into the catastrophic phase of the Part D benefit — a more than 10-fold increase from 2010.

AHIP believes that any regulatory change designed to lower out-of-pocket spending should be targeted to people taking these very expensive drugs. While many of these drugs unfortunately have no competition and offer no discounts, to the extent sponsors are able receive significant rebates for these drugs, a provision requiring that such rebates be applied to cost-sharing would at least provide a material benefit to such enrollees. At the same time, a targeted approach should minimize disruption to the Part D program, be operationally feasible with adequate transition time (beyond 2020), and limit the risk of significant increases in premiums or government costs.

Accordingly, AHIP recommends that CMS consider a regulatory proposal to require rebates be used to lower co-insurance costs for Part D enrollees taking drugs on a specialty tier, if the manufacturer of such drugs provides a material discount (e.g., 25 percent or higher). The rebates would be used to increase the portion of the negotiated price subsidized by the Part D plan. For example, reducing an enrollee’s cost sharing by 25 percent for a drug with a negotiated monthly price of $4,380 (the average price in the CBO report) would allow the enrollee to save $273.75 at the pharmacy counter while the drug is covered on the specialty tier.

At the same time, we continue to have serious concerns that applying the precise negotiated rebate amount to the enrollee’s cost sharing would help drug makers to reverse-engineer rebate levels that competitors have negotiated. This will give drug companies access to proprietary rebate levels that would have the anticompetitive effect of raising net prices and increasing costs to enrollees and the government. As such, we would recommend allowing Part D plans to aggregate and apply rebates across affected drugs in a way that would reduce cost sharing yet preserve the competitive dynamics of negotiated discounts.

As an alternative to this proposal, AHIP recommends that HHS consider implementing this proposal through an Innovation Center model. Applying certain rebates to reduce out-of-pocket costs at point-of-sale in a limited test could ensure that policymakers and stakeholders have a clearer understanding of the impacts and potential alternatives before such changes would expand into the entire Part D program.

65 See footnote 25.
2. Prohibition on Certain Types of Rebate Arrangements

As discussed elsewhere, based on significant evidence and the competitive nature of the Part D program, AHIP strongly believes that the current rebate structure does not create improper incentives for plans and contracted PBMs, nor does it cause high list prices and list price increases. Rather, drug prices are within the control of drug makers. Rebates are a response to those high prices, not a cause. However, we recognize HHS’ often-stated concern that rebates can, at least in some cases, create the perception that incentives are misaligned with encouraging the use of lowest cost drugs. Accordingly, AHIP offers two types of restrictions that HHS could consider adding as conditions to the existing safe harbor for rebates in Part D. These conditions would be more targeted than HHS’ proposed changes and, therefore, have less impact on the ability of plans and their contracted PBMs to negotiate with drug makers.

First, HHS could modify the current safe harbor to exclude rebate arrangements that are directly tied to prices, with a protection against mid-year price spikes. Plans and PBMs categorically support lower prices and lower net costs. However, there is a perception that certain plans or PBMs prefer price increases to price reductions because of the impact on rebate levels. This alternative proposal would eliminate that perception. Additionally, to protect against unexpected cost increases caused by mid-year price spikes, this proposal should be tied to the mechanism protecting against large price increases discussed below.

Second, the Administration has raised concerns about plans providing favorable formulary placement for brand drugs with higher list prices and higher rebate levels as compared to their authorized generics with lower list prices (yet no rebates). The Administration appears to believe this is inappropriate and can limit the development and use of generic drugs. AHIP strongly disagrees. Plans and their contracted PBMs simply favor the lowest net costs for covered drugs. This keeps costs as low as possible for seniors and taxpayers. Authorized generics are a way for drug makers to transition away from brand drugs while keeping prices of both products high. Nothing stops a drug maker from lowering the typically high cost of its authorized generic so its net cost would ensure more favorable formulary placement. This is exactly how Part D was designed to work, relying on private sector competition and negotiation to deliver the most cost-effective product possible. However, to address its concerns, HHS could modify the existing safe harbor for rebates to exclude rebate arrangements that tie a drug maker’s branded drug to a more favorable formulary placement and cost sharing if the net cost of the brand is higher than that of the authorized generic version. HHS could also apply this net cost requirement to reference biologics and their biosimilar alternatives. We steadfastly agree with the Administration that patients, consumers, and taxpayers deserve lower list prices as well as lower net costs and stand to deliver them for all Americans.

3. Mechanisms to Restrain Drug Price Increases

The Proposed Rule does nothing to ensure that the changes to Part D and Medicaid would instead lead to lower list prices. It assumes that rebates fuel higher list prices, and therefore, eliminating rebates would lead to lower list prices. The vast weight of the evidence of course suggests otherwise,
including the fact that egregious drug pricing behaviors by the drug industry occurred well before rebates became prevalent.\textsuperscript{66}

We recommend that HHS create a mechanism to hold drug makers responsible for egregious price increases, much like CMS has proposed to impose limits tied to price increases for protected class drugs. Absent such a mechanism to hold the drug industry accountable for their actions, there will simply be no incentive for drug makers to lower prices or to only make reasonable and fair price increases. For example, CMS could consider requiring, as a condition of participation in Part D, that drug makers limit annual list price increases to CPI-U, absent any science and evidence-based justification for such increases.