



April 8, 2019

Honorable Daniel R. Levinson
Office of the Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Impence Ave., SW
Washington, DC 20201

Attention: Aaron Zajic

Submitted via www.regulations.gov

Re: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals

Dear Mr. Levinson,

The Alliance of Community Health Plans (ACHP) applauds the administration's continued efforts to address the high cost of prescription drugs. ACHP is a national leadership organization bringing together health plans and provider organizations that are among America's best at delivering affordable, high-quality coverage and care. Members are non-profit plans active in 34 states and the District of Columbia, providing both private and public coverage to nearly 22 million Americans, including 2.6 million Medicare beneficiaries.

We appreciate the opportunity to comment on the Office of Inspector General's (OIG) proposed rule regarding the removal of safe harbor protections for rebates involving prescription drugs. The administration has offered a novel idea with the admirable goal of transparency in a system that to date has been muddy at best. We believe this proposal could help replace a broken system with one that allows competition and market forces to flourish for the benefit of healthcare consumers. With additional analysis and testing, we see the opportunity to reduce some of the current perverse incentives in today's system.

Every day, our nonprofit, community health plans are working hard on behalf of patients to hold down costs while ensuring access to the right therapies, at the right time at the right price. There are aspects of the current system that make that task exceedingly difficult, including a lack of transparency in how pharmacy benefit managers' (PBMs) operate. At the same time, we must reiterate that the central problem in our nation's pharmaceutical market today is price. It is not clear to ACHP or a wide swath of experts that the proposed changes to safe harbor protections will get at this root cause.

We share the administration's goal of reforming the way prescription drugs are priced and paid for, including the application of discounts or rebates. We agree the inappropriate use of rebates can create a

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financial incentive for PBMs to prefer higher-cost drugs to generate more revenue. Price trends suggest the current rebate system also creates a financial incentive for many manufacturers to increase a drug's list price. Ending these perverse incentives and creating a more transparent and efficient pricing system that drives down costs, especially for consumers, is an outcome that ACHP is committed to working with the administration to achieve.

While we support the intent of the proposal, our members have a number of questions and concerns. We urge the administration to provide additional time to discuss the proposal with health plans and other key stakeholders – and potentially pilot these concepts – before finalizing any changes.

We are encouraged by the guidance released by the Centers for Medicare and Medicaid Services (CMS) on Friday, April 5 that indicated, “if there is a change in the safe harbor rules effective 2020, CMS will conduct a demonstration that would test an efficient transition for beneficiaries and plans to such as change in the Part D program.”¹ We concur that absent additional consideration and testing the administration's intent may not be realized.

ACHP offers the following additional comments on the proposed regulation, which are explained in greater detail below.

- We are concerned by the uncertainty associated with the proposal and the effects that would occur if the regulation were implemented in its current form. Additional clarity is needed for our member plans to help the administration achieve its desired policy goal;
- The proposal creates a set of winners and losers. If implemented, the rule would potentially increase costs for beneficiaries and taxpayers. On the other hand, it provides a financial windfall for many pharmaceutical manufacturers, the industry responsible for today's high prices;
- Point of sale rebates could potentially undermine the Medicare Part D program and the measures plan sponsors have implemented to help control drug costs;
- ACHP believes there are new and innovative models used by pharmaceutical benefit managers the administration should consider further. These models are fully transparent, fee-based and share 100 percent of the discounts they negotiate with their clients. It is important to note these models exist under the current safe harbor framework. They have successfully ended the perverse incentive that exists under traditional PBM models in which drugs with higher list prices and higher rebates receive preferred treatment. (We reiterate our offer to provide the administration with an educational briefing by three such PBMs.)

The proposal in its current form would be challenging to implement.

There are a number of logistical challenges associated with implementing a proposal of this size and scope. Implementation of this proposal continues to be concerning to our members and could be extremely disruptive to nonprofit, community health plans if the administration does not continue to approach these reforms with a flexible mindset.

For instance, the rebate portion of our members' contracts with their pharmacy benefit managers will need to be renegotiated since it will invoke a material change clause. However, that renegotiation cannot occur

¹ Centers for Medicare and Medicaid Services, US Department of Health and Human Services. (2019, April 5). Guidance Regarding Part D Bids.

until after the safe harbor revision is finalized and our plans fully understand how to comply with the new regulatory framework being established. If the proposed rule is finalized, the contract renegotiation that would ensue includes a multi-step process in which PBMs would need to renegotiate with pharmaceutical companies and then with health plans.

Additionally, Medicare rebate contracts need to be completed 10 to 12 months prior to the plan year. Based on those contracts, plans create formularies and bid assumptions in March and April. As you know, the formulary needs to be complete by early May for June bid submission. Given where we are presently in the calendar year, none of this can be implemented for 2020.

Our members appreciate the recent guidance released by CMS that recognizes these constraints. However, we will need additional clarity on the pilot program the agency mentions, including implications for plans that may not participate in such a demonstration.

Additional clarity on the administration’s proposal is needed.

ACHP appreciates the great lengths the administration went through to determine the full impacts of the proposed regulation, including the production of several actuarial analyses. However, the studies commissioned by the Department of Health and Human Services arrived at different and sometimes conflicting conclusions making it difficult to ascertain the likely impact the regulation would have, let alone adjust accordingly.

For example, each of the analyses examined the impact on pharmaceutical manufacturers and the prices they set in a post-rebate scenario. The analysis developed by the CMS Office of the Actuary assumed, “15% of the existing manufacturer rebates for Medicare Part D and Medicaid supplemental rebates would be retained by drug manufacturers.”²

Conversely, the study conducted by Milliman assumed, “manufacturers would produce equivalent price concessions, whether through explicit reductions to list prices or through negotiated discounts reflected at the POS.”³

The Milliman study itself outlines seven different possible scenarios in how various stakeholders may behave in a post-rebate environment. These behavior changes have significant implications for how therapies will be priced and paid for. Accordingly, they should be better understood before any proposal moves forward.

ACHP also believes there needs to be more consideration of how drug manufacturers may alter their pricing strategies in reaction to the proposal, including longer-term impacts.

Under the proposed regulation, drug makers would still have the ability to increase prices at will in future years, as they currently do. Indeed, news reports in January detailed nearly 30 pharmaceutical companies intending to raise prices on about 60 therapies in defiance of President Trump’s call for a slowdown. We

² Center for Medicare and Medicaid Services (2018, August 30). *Proposed Safe Harbor Regulation [Memorandum]*. Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>

³ Milliman. (2019, January 31). *Impact of Potential Changes to the Treatment of Manufacturer Rebates*. Retrieved from: <https://aspe.hhs.gov/system/files/pdf/260591/MillimanReportImpactPartDRebateReform.pdf>

are concerned there is nothing in the proposed rule to address the problem of rapid and steep price increases, or the lack of transparency justifying those prices.⁴

Finally, we seek confirmation that the proposed safe harbor revisions apply exclusively to rebates provided by pharmaceutical manufacturers and not upfront discounts.

The proposal creates winners and losers and may result in unintended consequences.

ACHP is concerned about the cost burden that would be shifted to the Medicare program, which would shoulder most of the increased spending. According to the Milliman analysis, Medicare drug spending could increase by \$200 billion as a result of the rule.⁵ Medicaid, as well, would see higher costs under the proposal.⁶

ACHP does not believe that increasing the federal government’s expenditures for pharmaceuticals is an appropriate policy solution. The federal government spent approximately \$133 billion on retail prescription drugs in 2017 according to National Health Expenditures data.⁷

We fear adding to Medicare and Medicaid’s cost burden would lead to drastic cuts elsewhere in these programs, that could harm beneficiary access to needed services and care. Rather ACHP encourages the administration to pursue policies that bolster the negotiating authority of health plans, curb current pricing practices of drug manufacturers and reform payment policies to incentivize the utilization of lower cost, higher value therapies.

We are also concerned about the financial impact the proposed regulation will have on beneficiaries. As the CMS analysis notes, “though average beneficiary costs would decrease, the majority of beneficiaries would see an increase in their total out-of-pocket and premium costs. The minority of beneficiaries who utilized drugs with significant manufacturer rebates would experience a substantial decrease in costs, causing average beneficiary cost across the program to decline.”⁸

It is possible the savings expected to flow to enrollees with high-drug costs under the proposal may not actually materialize. Manufacturers may have little incentive to discount high-cost drugs that lack competition and account for a significant portion of drug spending. As noted in a recent JAMA op-ed, “Under the new proposal, even if manufacturers converted their rebates to upfront discounts, only those patients who are taking drugs in competitive classes would realize savings, while patients taking some of the most expensive medications would not.”⁹

⁴ NBC News. (2019, January 2). Defying Trump, drugmakers hike prescription drug prices for 2019. Retrieved at: <https://www.nbcnews.com/business/business-news/defying-trump-drugmakers-hike-prescription-drug-prices-2019-n953756>

⁵ Ibid.

⁶ Ibid.

⁷ Centers for Medicare and Medicaid Services (CMS). National Health Expenditures Data. Retrieved at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>

⁸ Center for Medicare and Medicaid Services (2018, August 30). *Proposed Safe Harbor Regulation [Memorandum]*. Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>

⁹ Dusetuzina, S. and Bach, P. (2019, March 6). Prescription Drugs—List Price, Net Price, and the Rebate Caught in the Middle. JAMA. Retrieved at: <https://jamanetwork.com/journals/jama/fullarticle/2727874>.

Furthermore, ACHP understands that the administration believes health plans and PBMs will be able to keep premiums stable. However, many of our member plans anticipate the need to increase premiums to account for higher pharmaceutical costs. According to the CMS actuary's analysis, "premiums for households would increase by \$50 billion— an expense that would be borne by Medicare Part D enrollees."

The proposal would increase profits for drug makers, those responsible for setting today's high prices.

The proposal would potentially raise costs for stakeholders across the healthcare system with one exception: drug companies. As CMS' actuarial analysis notes, "pharmaceutical manufacturers would benefit from the proposed rule overall, even as list prices were reduced."¹⁰

Specifically both the Wakely and the CMS analyses estimate that drug manufacturers will experience large decreases in their coverage gap discount obligation. The CMS study specifies, "the proposal would give manufacturers an opportunity to recapture some of the forgone revenue streams such as those that occurred from the changes in the Coverage Gap Discount Program included in the Bipartisan Budget Act of 2018."¹¹ CMS estimates a \$40 billion savings to drug makers due to this effect.¹²

ACHP is skeptical that the savings that flow to drug makers will be fully used to lower list prices to the benefit of health plans and the beneficiaries we serve. Again, there is nothing in the proposed regulation that requires manufacturers to lower list prices on net with the rebates they are currently providing.

Point-of-sale rebates are not a solution to high drug costs.

ACHP is concerned that by incorporating rebates at the point-of-sale, plan premiums would increase over current policy projections, which would have a detrimental impact on beneficiaries and the Part D program overall.

Premiums are a major driver of beneficiary Part D plan decisions, not only their choice of a specific Part D plan but whether to participate at all. Significant increases to Part D premiums, in the absence of other policy changes to reduce out-of-pocket costs, would likely lead to fewer seniors enrolling, with the effect of reducing Medicare beneficiary access to prescribed medications. In addition, the resulting deterioration of the risk pool could erode the long-term sustainability of the Part D program.

We also believe that a requirement to reflect manufacturer rebates in the point-of-sale would influence enrollee behavior and undermine drug utilization tools that health plans have put in place to manage costs. Specifically, point-of-sale rebates may actually increase the use of expensive drugs further driving up total cost. This is already a major issue in commercial markets, where drug companies are paying copays and deductibles and driving the benefit to 100% coverage without any out-of-pocket expense.

With no out-of-pocket costs, there are strong incentives for a beneficiary to use a high cost drug when a lower cost alternative is available, thereby circumventing cost-control measures a plan has instituted to

¹⁰ Center for Medicare and Medicaid Services (2018, August 30). *Proposed Safe Harbor Regulation [Memorandum]*. Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>

¹¹ Ibid.

¹² Ibid.

manage drug spending. It is for this reason that federal regulators have prohibited drug coupons in federal programs. Allowing rebates at the point-of-sale has the potential to undermine that existing policy.

Alternative models exist with proven track records on reducing costs.

Again, ACHP agrees with the administration's intent to create a more transparent pharmacy benefits model that drives costs out of the system. Moving to such a system, however, would take considerable time and effort from stakeholders across the supply chain.

We believe such models already exist that can be instructive to the administration. Several ACHP member plans have established PBMs that pass 100 percent of the rebates they secure back to clients. These models rely on a flat administrative fee in exchange for their services, instead of a percentage of the list price. Furthermore, these PBMs are fully transparent, so their business practices and revenue streams are completely visible. There are no hidden fees or black boxes.

It is important to note that these models exist under the current safe harbor framework. The reason they have been successful is not because they have stopped using rebates to reduce drug costs. Rather it is due to their efforts to delink how they earn revenue from the list price of a drug. These models have successfully ended the perverse incentive that exists under traditional PBM models in which drugs with higher list prices and higher rebates receive preferred treatment.

The results speak for themselves. Pharmacy Benefits Dimensions (PBD), the PBM arm of Independent Health, has been able to significantly reduce pharmacy costs for their customers nationwide by up to 30 percent in just one year. In the case of one employer served by PBD, per-employee per-month spending was reduced from \$169 to \$69, saving that employer over \$300,000 in its overall pharmacy drug spend and significantly bending the trend on employee costs.

These savings can be used by health plans in a variety of ways, including to reduce plan spend and/or providing member savings, such as offsetting premium costs. Copays also can be lowered for enrollees under alternative models that do not charge an enrollee more than the cost of the drugs themselves. This simple but important business practice can result in significant annual savings for patients depending on their drug regimen.

Unfortunately, the proposed rule does not account for these new and innovative models that are taking place within the PBM industry. The regulation could limit the flexibilities of health plans to utilize rebates in a way that delivers high value pharmacy benefits to health plans and consumers.

These limitations would come on top of an uneven playing field in which some PBMs operate a fully transparent model and others do not. As this administration knows well, PBMs that are fully transparent often find themselves at a competitive disadvantage relative to PBMs that cloak their business practices and revenue models.

We encourage the administration to pursue policies that encourage fully transparent, fee-based models focused on providing the savings back to customers. For instance, the administration could work with state Medicaid programs to support this approach through new incentives or demonstration projects. Ohio's Medicaid program has already issued a mandate that requires managed care health plans to renegotiate PBM contracts to transition from a spread-pricing drug purchasing model to a pass-through model. The Department could take a leadership role in facilitating other states to follow Ohio's lead.

Prices set by manufacturers and dwindling competition continue to drive pharmaceutical costs higher.

Finally, we believe more needs to be done to address the fact that drug manufacturers are solely responsible for setting the price of pharmaceuticals in the United States. Pharmaceutical companies' ability to dictate price has increased as competition has decreased; partially due to tactics deployed by drug makers themselves. Pharmaceutical companies' aggressive tactics to preserve their monopoly power have led to delayed entry of competitors into the market and allowed them to maintain unjustifiably high prices.

Recent data released by CMS shows that there are a number of drugs for which there is only a single manufacturer and contribute significantly to Medicare's pharmaceutical expenditures. For the top 30 drugs prescribed in Medicare Part D, each had a single manufacturer and cost Medicare nearly \$1 billion in 2017.¹³

ACHP supports additional efforts to bring more competition to pharmaceutical pricing, including reining in abuses by drug makers that hinder new products from entering the marketplace. We urge the administration to put its weight behind measures, such as the bipartisan CREATES Act and transparency requirements, that would immediately remedy some of these well-known problems.

Conclusion

Thank you for consideration of ACHP's recommendations. We welcome the administration's continued engagement on this issue and look forward to working together to enact real and long-lasting change on behalf of American patients. Please contact me at cconnolly@achp.org if you have questions or require additional information.

Sincerely,



Ceci Connolly
President and CEO

¹³ Centers for Medicare and Medicaid Services, US Department of Health and Human Services. Drug Dashboard. Retrieved at: https://portal.cms.gov/wps/portal/unauthportal/unauthmicrostrategyreportslink?evt=2048001&src=mstrWeb.2048001&documentID=203D830811E7EBD80000080EF356F31&visMode=0¤tViewMedia=1&Server=E48V126P&Project=OIPDA-BI_Prod&Port=0&connmode=8&ru=1&share=1&hiddensections=header,path,dockTop,dockLeft,footer