Don't Disrupt Drug Coverage for 48 Million Americans on Hope Alone

If the U.S. Department of Health and Human Services (HHS) finalizes the 2019 regulation on safe harbors for prescription drug price concessions, Medicare Part D premiums will increase for all those who pay them. While such a proposal may help a small portion of beneficiaries with very high drug costs, it would push those costs onto older Americans and taxpayers still struggling with the effects of the coronavirus pandemic and economic distress.[i]

Eliminating manufacturer rebates would do nothing to address drug prices. The administration has continually stated its goal to lower prescription drugs list prices,[ii] and yet the proposed rule could only speculate that manufacturers *might* do so. Centers for Medicare & Medicaid Services (CMS) actuaries predicted manufacturers would keep at least 15 percent of what they would have offered in rebates. Further, these same estimates showed the proposed rule would have increased prescription drug spending by $137 billion.[iii] The fact is manufacturers—and only manufacturers—set drug prices.

Part D premiums and out-of-pocket costs will increase, potentially dramatically.

- **Analysts from the Congressional Budget Office (CBO), CMS, and Avalere Health agreed that premiums would increase between 25 and 40 percent.**[iv] If premiums increased 25 percent, as suggested by CMS' Office of the Actuary (OACT),[v] the average annual premium would have increased by more than $100 in 2020 and future years.[vi] This would mark the largest average premium increase in the history of the Part D program.
- **Analysts at Avalere Health found the proposal would increase out-of-pocket costs by as much as $36.5 billion.**[vii] While approximately 10 percent of beneficiaries would save more on cost sharing than they spend on premiums, the other 90 percent would pay more.[viii]
- **Because Part D is voluntary, reissuing the 2019 proposed rule could destabilize the program if higher premiums and out-of-pocket costs cause healthier beneficiaries to drop coverage or never sign up at all.**

According to CBO, CMS, and Avalere Health, the 2019 proposed rule would have cost taxpayers between $200 and 400 billion.[ix] OACT estimated the cost at nearly $200 billion over 10 years,[x] making it one of the most expensive regulations in history.[xi]

The administration likely went shopping for actuarial results it wanted. Only after the OACT report was delivered did a private actuarial firm provide the administration a separate report running six alternate scenarios. The administration selected four to cite, two of which indicated significant savings, while the other two suggested large costs.[xii] In the 2019 regulation, the administration cited six actuarial cost estimates by three different actuarial organizations.[xiii] These studies projected that the regulation would either *cost* taxpayers $196 billion or *save* them $100 billion, or fall somewhere in between. In the regulation's impact description, the administration uses the word "if" 40 times to describe what might or might not happen.

Antitrust case law may still deter manufacturers from offering up-front discounts. If reissued as an Executive Order, nothing in the rule would address the fact that manufacturers could

cite antitrust law as the reason not to give volume-based, up-front discounts. In that case, there would be no viable alternatives to the rebate system that drug manufacturers themselves created.

Eliminating rebates relies on the hope that manufacturers lower their prices. Even if the intent of such an Executive Order were to reduce consumer costs, it does not mean that it will. Manufacturers already could lower their list prices and choose not to, and prices continue to rise in Medicare Part B, a program which does not involve negotiated rebates. If manufacturers do not voluntarily lower their list prices, the Department of Health and Human Services has acknowledged that the proposal would result in large increases in both federal subsidies and Medicare beneficiary premiums, with major benefits accruing to manufacturers in the form of higher profits.

The timeline is entirely unworkable. Plans and PBMs have already submitted bids for plan year 2021. There is no way to amend these filings to properly reflect the associated costs, and it would be impossible to revise manufacturer agreements and retool the supply chain in such a short period of time. Further, beneficiary coverage information would have to be completely rewritten and Plan Finder revised to go live in less than three months, sowing much potential confusion during the Part D Open Season shopping period, which begins October 15, 2020.

State Medicaid programs could lose billions; pharmacies could be left holding the bag. The 2019 proposal did not quantify effects on state Medicaid programs or community pharmacies. At a time when states are facing budget shortfalls, state Medicaid programs could lose billions in annual revenues from drug manufacturers through reduced statutory rebates. In addition, under current processing timelines, pharmacies could be waiting for billions of dollars in chargebacks from manufacturers for Part D claims, leaving many in precarious financial straits.

Drug manufacturers would receive a bailout. The fact that both PhRMA "applaud[ed]"[xiv] and BIO "strongly support[ed]"[xv] the 2019 proposed rule should reinforce that manufacturers—not beneficiaries and taxpayers—would have been the big winners under the rule. It would have increased prescription drug spending by $137 billion.[xvi] And with drug manufacturers retaining the discounts they currently pay in the form of rebates, they also would have stood to receive a bailout of between $40 and $100 billion over 10 years.[xvii]

---

[i] Congressional Research Service (CRS). Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs). June 15, 2017. https://crsreports.congress.gov/product/pdf/R/R44264

[ii] See, e.g., Stat News, "Alex Azar: Why Drug Prices Keep Going Up — And Why They Need to Come Down." January 29, 2019. https://www.statnews.com/2019/01/29/lowering-drug-prices-trump-alex-azar/

[iii] CMS OACT, "Subject: Proposed Safe Harbor Regulation." (August 30, 2018).

[iv] CBO, "Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Materials for *Updated Budget Projections: 2019 to 2029*." May 2019; and Avalere Health. "Costs for Taxpayers Could Skyrocket Under Proposed Rebate Rule." April 8, 2019. https://www.ahip.org/costs-for-taxpayers-could-skyrocket-under-proposed-rebate-rule/

[v] OACT, Op. Cit.

[vi] 2018 Medicare Trustees Report, p. 198. June 5, 2018.

[vii] Avalere Health, Op. Cit.

[viii] Cathy Kelly, Pink Sheet. "Point-of-Sale Rebates in Part D: Study Highlights Trade-Offs for Medicare." June 29, 2017. https://pink.pharmaintelligence.informa.com/PS120984/PointOfSale-Rebates-In-Part-D-Study-Highlights-TradeOffs-For-Medicare

[ix] CBO, OACT, and Avalere Health, Op. Cit.

[x] OACT, Op. Cit.

[xi] American Action Forum. "Mandating Talking Cars: Costliest and Most Beneficial?" December 16, 2016. This article describes what were, at the time, the two costliest proposed regulations in U.S. history. The OACT cost estimate for the administration's proposal is in excess of these two. https://www.americanactionforum.org/regulation-review/mandating-talking-cars-costliest-beneficial/

[xiv] Pharmaceutical Research Manufacturers of America (PhRMA). "PhRMA Statement on the Administration's Proposed Rule to Reform the Rebate System." January 31, 2019. https://www.phrma.org/press-release/phrma-statement-on-the-administration-s-proposed-rule-to-reform-the-rebate-system

[xv] Biotechnology Innovation Organization (BIO). "BIO Statement on New Proposal for Lowering Out-of-Pocket Costs for Medicines." January 31, 2019. https://www.bio.org/press-release/bio-statement-new-proposal-lowering-out-pocket-costs-medicines
[xvi] OACT, Op. Cit.
[xvii] OACT and Avalere Health, Op. Cit.