

Questions about Proposals to Shift Drug Coverage from Medicare Part B to Medicare Part D That Would Increase Prices for Millions of Medicare Enrollees

Our July 11, 2018 letter¹ indicated that we have a number of concerns with the Administration's proposal to switch drug coverage from Medicare Part B to Medicare Part D. In particular, we are concerned that the proposed shift of drug coverage for seniors from Medicare Part B to Medicare Part D would (1) leave millions of seniors who do not have Medicare Part D drug coverage with no apparent source of insurance for these drugs; (2) increase co-pays and out-of-pocket costs for the drugs, because many drug co-pays under Medicare Part D are higher than the 20% co-pays for drugs under Medicare Part B; and (3) provide seniors with no protection from runaway drug prices. These costs would be exacerbated by Administration proposals to impose new out-of-pocket costs on seniors in the Part D program.

1. What drugs or classes of drugs is the Administration proposing to switch or considering switching from Part B coverage to Part D coverage?
2. What evidence does the Administration have that this switch will result in lower prices for seniors?
3. To what extent do Medicare Part D plans effectively negotiate lower drug prices?
 - a. For all brand-name drugs, what is the average percentage manufacturer rebate and discount obtained by Medicare Part D plans? For this same group of drugs, please list changes in the average net price and the percentage change in average net price increases over the past five years.
 - b. For the 100 highest selling brand-name drugs by dollar sales, what is the average percentage manufacturer rebate and discount obtained by Medicare Part D plans? For this same group of drugs, please list changes in the average net price and the percentage change in average net price increases over the past five years.
 - c. For all specialty drugs, what is the average percentage manufacturer rebate and discount obtained by Medicare Part D plans? For this same group of drugs, please list changes in the average net price and the percentage change in average net price increases over the past five years.
 - d. For all cancer drugs, what is the average percentage manufacturer rebate and discount obtained by Medicare Part D plans? For this same group of drugs, please list changes in the average net price and the percentage change in average net price increases over the past five years.
4. How many Medicare recipients nationwide have Medicare Part B drug coverage but do not have Medicare Part D drug coverage? How many recipients in each state have Medicare Part B drug coverage but do not have Medicare Part D drug coverage?
5. If drugs are switched from Medicare Part B to Medicare Part D, how will the Administration address the lack of coverage and increased drug costs for the millions

¹ Letter from Senators Warren and Smith to Alex Azar, Secretary, Department of Health and Human Services, July 11, 2018, <https://www.warren.senate.gov/imo/media/doc/Letter%20to%20Azar.pdf>.

of beneficiaries who do not have Part D drug coverage?

6. How many Medicare Part B recipients currently have Medicare supplemental plans that help cover the co-pays or other Part B prescription drug costs? If drugs are switched from Medicare Part B to Medicare Part D, how will the Administration address increased drug costs for these beneficiaries?
7. All approved drugs are available under Medicare Part B, but drug plans can impose formularies and other coverage restrictions under Medicare Part D.
 - a. Of the top 100 most popular Part D drugs (by dollar sales), how many have formulary restrictions (such as prior authorization, etc.) imposed by one or more available Part D plans?
 - b. If seniors use a drug under Part B that has a formulary restriction on Part D coverage, how will you ensure that seniors do not lose access to this drug or pay higher costs if their coverage is switched from Part B to Part D?
8. Under Medicare Part B, seniors pay a 20% coinsurance rate, but under Part D, coinsurance can be as high as 40% – and the most expensive specialty drugs have the highest co-insurance rates.
 - a. Please describe the range of coinsurance rates that seniors experience under Part D plans?
 - b. Of the top 100 most popular Part D drugs (by dollar sales), how many have coinsurance costs of more than 20% under one or more available Part D plans?
 - c. How will you ensure that seniors are protected from higher coinsurance costs if drug coverage is switched from Part B to Part D?
9. The Administration has proposed "exclude[ing] manufacturer discounts from the calculation of beneficiary out-of-pocket costs in the Medicare Part D coverage gap," also known as the "true out-of-pocket" cost or TROOP.²
 - a) For the average senior, how much will the changes to the TROOP calculation increase drug spending under Medicare Part B?
 - b) Has the CMS Actuary conducted any analyses about the taxpayer savings or costs for seniors as a result of this proposal? What have these estimates revealed?
 - c) How many seniors will pay higher costs as a result of the changes to the TROOP calculation?
 - d) Please provide copies of all CMS Actuary estimates or any other estimates of the cost of modifying the TROOP calculations for seniors, including estimates that indicate the distributional effects of these changes.

² Budget of the U.S. Government for Fiscal year 2019, p. 127, <https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf>.

10. In 2005, when you were a high-ranking official at HHS, the Bush Administration rejected the idea of shifting drugs from Part B to Part D, saying that “such a change would not be desirable for most categories of Part B drugs” and raising concerns around the financial implications for many Medicare beneficiaries.³ What new information has the Administration obtained that indicates that such a change would now be appropriate?
11. Analysts have indicated that the proposed switch from Part B to Part D would “significantly increase out-of-pocket costs for some of the sickest people on Medicare.”⁴ Can you assure us that this will not happen? Specifically, can you provide assurances that no senior will pay higher drug costs under a potential switch of drug coverage from Part B to Part D?

Questions about Whether the Drug Industry Will Voluntarily Reduce Prices

Our June 11 letter raised questions about President Trump’s promises that drug manufacturers would voluntarily reduce prices and that this would help solve the problem of high drug prices. We ask that you provide answers to the following questions on the drug industry’s voluntary efforts to reduce prices:

1. What did President Trump mean when he stated that “We’re going to have some of the big drug companies in in two weeks and they’re going to announce ... voluntary massive drops in prices”? When will this announcement be made?
2. What individuals in the Administration have met with drug manufacturers to discuss voluntary proposals? What has been the nature of these discussions?
3. What specific commitments on pricing have you obtained from drug manufacturers?
4. What is the nature of these voluntary proposals? Will these voluntary agreements reduce prices on drugs that cost the most or contribute the most to overall spending?
5. How will the Administration ensure that drug manufacturers do not break any of the voluntary pledges they may make to reduce drug prices or to constrain price increases?
6. Who from the Administration is negotiating with or communicating with drug manufacturers with regard to voluntary price reductions?
 - a. Please provide a list of all meetings, phone calls, or other communications between Administration officials and drug manufacturers about voluntary drug price reductions.

³ HHS, Report to Congress Transitioning Medicare Part B Covered Drugs to Part D, 2005, (https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/RtC_PtBtoPtD_2005_4.pdf).

⁴ *New York Times*, “Trump Plan to Lower Drug Prices Could Increase Costs for Some Patients,” June 2, 2018, www.nytimes.com/2018/06/02/us/politics/medicare-drug-costs.html.

- b. Please provide copies of all e-mail or other communications between Administration officials and drug manufacturers about voluntary drug price reductions.
- c. Were drug manufacturers offered any policy or political concessions or any kind of quid quo pro by the Administration in exchange for voluntarily reducing prices? Did any HHS or Administration officials agree to support (or withhold support for) any legislative or administrative proposals to reduce prices in exchange for voluntary reductions in prices?

Allegations about Pharmacy Benefit Managers and Drug Distributors Acting to Prevent Voluntary Price Reductions

At the June 12 hearing, Senator Warren asked, “Which drug companies will be voluntarily lowering their prices?”⁵ You indicated that multiple drug companies were considering doing so, but were running into opposition and roadblocks from pharmacy benefit managers (PBMs) and drug distributors. You stated that:

There are actually several drug companies that are looking at substantial and material decreases of drug prices. ... They’re working right now with the pharmacy benefit managers and distributors. ... What they’re trying to do is work to ensure they’re not discriminated against for lowering their prices. You should focus ... on the PBMs and distributors who might say to these [drug companies] do not decrease your price.⁶

You later clarified:

We’ve had several drug companies come in who ... want to execute substantial material reductions in their drug prices. They’re finding hurdles from pharmacy benefit managers and distributors ... where they might say if you decrease your list price, I will take you off formulary compared to your competitor.⁷

You also suggested that:

[E]mployers and payer customers of PBMs ... should be asking their PBMs right now, have you received any commitments of lower list prices and what have you

⁵ Sen. Elizabeth Warren, The Cost of Prescription Drugs: Examining the President’s Blueprint ‘American Patients First’ to Lower Drug Prices, Committee on Health, Education, Labor, and Pensions, June 12, 2018, <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan>.

⁶ HHS Secretary Alex Azar, The Cost of Prescription Drugs: Examining the President’s Blueprint ‘American Patients First’ to Lower Drug Prices, Committee on Health, Education, Labor, and Pensions, June 12, 2018, <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan>.

⁷ HHS Secretary Alex Azar, The Cost of Prescription Drugs: Examining the President’s Blueprint ‘American Patients First’ to Lower Drug Prices, Committee on Health, Education, Labor, and Pensions, June 12, 2018, <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan>.

done ... and are you pushing back on drug companies saying you would prefer higher list drug prices?”⁸

1. Is the Administration in possession of any specific evidence or information that any PBM or drug distributor is “pushing back on drug companies” or otherwise setting up a “hurdle” to reducing drug prices?
 - a. If so, please describe this information.
 - b. If so, which companies are creating barriers to lower drug prices and how specifically are they preventing drug companies from voluntarily lowering prices?
2. If PBMs or drug distributors are establishing these hurdles, what is the Administration doing to address this dynamic?
3. Have CMS or Administration officials referred any of this activity by PBMs or drug distributors to the Inspector General, to DOJ, to FTC, or to any other authority to investigate these behaviors?

Questions about Runaway Drug Company Profits and CEO Pay

Our June 11 letter raised concerns about runaway drug company profits and drug company CEO pay and noted that current trends in drug company profits and CEO pay appear to remain untouched by the Administration’s proposals. We ask that you provide answers to the following questions regarding the impact of the Administration’s drug pricing plan on drug company profits and the compensation of pharmaceutical company executives.

On the day President Trump announced his proposal, drug company stocks “soared”⁹ – a reaction to the details of the plan, which largely stick to PhRMA-approved policies and fail to contain key proposals like government price negotiation or allowing seniors to import less expensive drugs from other countries that obtain lower prices. Overall, analysts described the plan as being “very, very positive to pharma.”¹⁰

You claimed that “stock analysts, who are really quite smart individuals generally, totally missed the boat here” and urged them to “do a bit more reading and looking, listening and understanding” in order to grasp how tough the plan was on the drug industry.¹¹

1. What do you believe stock analysts got wrong in their assessment of the President’s drug pricing proposal? Did the administration expect stock prices to decline following the President’s announcement on May 11?

⁸ HHS Secretary Alex Azar, The Cost of Prescription Drugs: Examining the President’s Blueprint ‘American Patients First’ to Lower Drug Prices, Committee on Health, Education, Labor, and Pensions, June 12, 2018, <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan>.

⁹ STAT, “Trump Promised to Bring Pharma to Justice. His Speech Sent Drug Stocks Soaring,” May 11, 2018, <https://www.statnews.com/2018/05/11/trump-drug-pricing-speech-stocks/>.

¹⁰ *New York Times*, “Trump Promises Lower Drug Prices, but Drops Populist Solutions,” May 11, 2018, <https://www.nytimes.com/2018/05/11/us/politics/trump-prescription-drugs-plan.html>.

¹¹ *Politico*, “Azar to Drug Plan Critics: Bring on the Fight,” Dan Diamond, May 17, 2018, <https://www.politico.com/story/2018/05/17/alex-azar-drug-plan-lower-price-critics-596966>.

2. What impact do you anticipate the implementation of the President's drug pricing proposal will have on pharmaceutical company profits? What evidence did you rely on in making this assessment?
3. Do you think it's fair that drug companies rake in such high profits given much of the research underpinning their products and new drug development generally is funded by taxpayers?
4. Do you believe that drug company CEO compensation is too high? What policies is the Administration considering, if any, to lower CEO pay at drug companies?

PhRMA's Influence on the Drug Pricing Plan

Our June 11 letter raised concerns about the role of PhRMA's influence on the drug pricing plan, and the fact that a former drug industry lobbyist had key responsibilities for key parts of the plan.¹²

Politico reported that Mr. Grogan "convened the first meeting on the administration's drug pricing policies in mid-April 2017 with a half dozen senior Health and Human Services officials, then led at least a dozen follow-up meetings through June to develop the plan,"¹³ and that "in his position at OMB, Grogan would shape or have a say over efforts to lower the price Medicare pays for drugs or to modify its prescription drug benefit. He'd also play some part in FDA initiatives to increase competition among different classes of medicines."¹⁴

In addition to Mr. Grogan, other industry lobbyists or executives working closely on the drug plan "include Dan Best, a former CVS vice president who is now heading up drug pricing efforts at HHS and Lance Leggitt ... [the] deputy director of the White House Domestic Policy Council, who represented drug companies while overseeing health care lobbying at Baker Donelson. John O'Brien, a staffer in [your] immediate office who is primarily supporting HHS' Medicare initiatives, worked for PhRMA earlier in his career."¹⁵

We ask that you provide answers to the following questions on the development of the Administration's drug plan.

1. Which individuals at HHS or elsewhere in the Administration were responsible for developing and approving the final list of proposals included in the Administration's drug pricing plan?

¹² Politico, "Former Drug Industry Lobbyist Helps Steer Trump Drug Plan," May 27, 2018, <https://www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170>.

¹³ Politico, "Former Drug Industry Lobbyist Helps Steer Trump Drug Plan," May 27, 2018, <https://www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170>

¹⁴ Politico, "Former Drug Industry Lobbyist Helps Steer Trump Drug Plan," May 27, 2018, <https://www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170>.

¹⁵ Politico, "Former Drug Industry Lobbyist Helps Steer Trump Drug Plan," May 27, 2018, <https://www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170>.

2. Did Joe Grogan play a role, and if so, what was this role? Similarly, what were the specific roles and responsibilities of Dan Best, Lance Leggitt, and John O'Brien?
3. Did any other Administration staff who formerly worked for or lobbied for drug manufacturers play a role in the development of the drug plan? If so, please describe their roles.
4. How many meetings have you and your staff held with drug manufacturers during the development of the drug proposal? Please provide a list off such meetings, and all participants.
5. How many meetings have you had with organizations representing seniors and other consumers? Please provide a list off such meetings, and all participants.
6. What policies have you implemented to prevent HHS staff from taking actions that may benefit their former employers or companies that they lobbied for or represented before joining the Administration?
7. Did you or did any HHS official have any communication with Michael Cohen, or with any individual purporting to represent Mr. Cohen or Essential Consultants, about drug pricing or any other prescription drug policy issue?

Questions about the 340B Drug Pricing Program

1. What specific changes to the 340B program are under consideration by the Administration?
 - a. Is the Administration considering changes that would reduce the number of eligible 340B entities?
 - b. Is the Administration considering changes that would reduce the number of patients for which eligible entities could receive discounts?
 - c. Has the Administrations sought input on either of these issues in the drug pricing blueprint? If so, why?
2. One question raised in the blueprint is whether the 340B program has [quote] “caused cross-subsidization by increasing list prices applicable in the commercial sector?”
 - a. Why did the Administration ask for input on this issue?
 - b. Does HHS have any analysis or information indicating that there is cross-subsidization?
 - c. Does HHS have any analysis or information indicating that restricting the number of eligible 340B entities or the number of patients for which 340B entities can receive discounts will have any impact on drug prices for other purchasers?