

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051

MINORITY (202) 225-5074

<http://oversight.house.gov>

May 23, 2019

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue S.W.
Washington DC, 20201

Dear Mr. Secretary:

We are continuing to conduct oversight of government policies affecting drug prices in the United States. The Department of Health and Human Services (HHS) recently issued a proposal to modify how pharmaceutical benefit managers (PBMs) handle rebates within Medicare and Medicaid.¹ The proposed rule threatens to raise Medicare Part D premiums, leading the Centers for Medicare and Medicaid Services (CMS) to announce a “demonstration project” in which the government would assume 95 percent of insurance company losses caused by the rule.² These actions amount to using a demonstration project to finance a taxpayer-funded bailout—which Republicans rightly criticized when HHS attempted it during the Obama Administration.³

In February 2019, HHS and its Office of Inspector General (OIG) published a proposed rule to remove certain prescription drug rebates from the safe-harbor protection under the Anti-Kickback statute.⁴ Specifically, the rule would eliminate the safe harbor for rebates to insurers and PBMs for Medicare Part D prescription drugs and Medicaid managed care plans, but not private-employer-based insurance.⁵ Instead, HHS proposed a new safe harbor for discounts at the point-of-sale for beneficiaries, beginning in January 2020.⁶

CMS anticipates that the propose rule will raise Medicare Part D premiums. The Office of the Actuary estimated that it would increase Part D premiums from between \$3.20 and \$5.64 per beneficiary per month in 2020.⁷ The Office of the Actuary also estimated that the proposed

¹ Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals, 84 Fed. Reg. 2340 (proposed Feb. 6, 2019) (to be codified at 42 C.F.R. 1001).

² Centers for Medicare & Medicaid Servs., Guidance Regarding Part D Bids (Apr. 5, 2019).

³ John Fund, *Obamacare's Hidden Switcheroo*, NAT. REVIEW (Oct. 21, 2012) <https://www.nationalreview.com/2012/10/obamacares-hidden-switcheroo-john-fund/>.

⁴ Safe Harbor, *supra* note 1.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

rule would increase total federal spending by \$196 billion from 2020 to 2029.⁸ Likewise, the Congressional Budget Office (CBO) estimated the proposed rule would cost \$177 billion over the next decade.⁹

On April 5, 2019, CMS Administrator Seema Verma announced that CMS would conduct a two-year “demonstration project” if the proposed rule went into effect in 2020.¹⁰ Under the demonstration project, CMS guaranteed that the federal government “would bear or retain 95% of the deviation between the target amount . . . and the actual incurred costs . . . beyond the first 0.5%” in 2020.¹¹ In other words, federal taxpayers would assume the risk of insurance company losses caused by the proposed rule. CBO estimated that this project—which it dubbed a “loss-absorption program”—would increase federal spending by \$10 billion.¹²

This is not the first time that HHS has sought to use a demonstration project to finance a taxpayer-funded bailout. As signed into law, Obamacare mandated drastic cuts to the Medicare Advantage program, which allowed Medicare-eligible seniors to choose a private health plan.¹³ In 2010, CMS announced an \$8 billion demonstration project to subsidize the Medicare Advantage program through quality bonus payments.¹⁴ In a July 2012 letter to then-Secretary Kathleen Sebelius, the Government Accountability Office (GAO) raised concerns about the demonstration project and questioned HHS’s authority to initiate the project.¹⁵ This Committee conducted oversight of this bailout during the Obama Administration.¹⁶

To assist the Committee in evaluating the proposed rule and the loss-absorption program, I respectfully ask that you provide the following documents as soon as possible but no later than June 6, 2019:

1. All documents and communications referring or relating to the memorandum issued from Administrator Seema Verma on April 5, 2019, titled “Guidance Regarding Part D Bids”; and
2. All documents and communications between or among HHS employees, insurance companies, or prescription drug manufacturers referring or relating to:

⁸ Centers for Medicare & Medicaid Servs., Off. of the Actuary, Memorandum on Proposed Safe Harbor Regulations (Aug. 30, 2018).

⁹ CONG. BUDGET OFF., INCORPORATING THE EFFECTS OF THE PROPOSED RULE ON SAFE HARBORS FOR PHARMACEUTICAL REBATES IN CBO’S BUDGET PROJECTIONS—SUPPLEMENTAL MATERIAL FOR UPDATED BUDGET PROJECTIONS: 2019 TO 2029 (2019).

¹⁰ Guidance, *supra* note 2.

¹¹ *Id.*

¹² SUPPLEMENTAL MATERIAL, *supra* note 9.

¹³ PATIENT PROTECTION AND AFFORDABLE CAR ACT, 42 U.S.C. § 18001 (2010).

¹⁴ U.S. GOV’T ACCOUNTABILITY OFF., B-323170, MEDICARE ADVANTAGE QUALITY BONUS PAYMENT DEMONSTRATION (2012).

¹⁵ *Id.*

¹⁶ Fund, *supra* note 3; Kyle Cheney, *Issa Subpoenas Medicare Documents*, POLITICO (Oct. 22, 2012) <https://www.politico.com/story/2012/10/issa-subpoenas-documents-on-medicare-demo-082715>.

The Honorable Alex M. Azar II

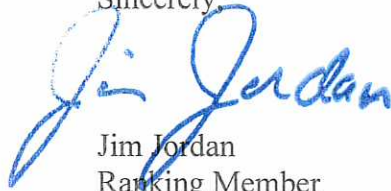
May 23, 2019

Page 3

- a. The proposed rule published on February 6, 2019, at 84 Fed. Reg. 2340; or
- b. The memorandum issued from Administrator Seema Verma on April 5, 2019, titled "Guidance Regarding Part D Bids."

If you have any questions about this request, please contact Committee staff at (202) 225-5074. Thank you for your attention to this matter.

Sincerely,



Jim Jordan
Ranking Member

cc: The Honorable Elijah E. Cummings, Chairman

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May 23, 2019

The Honorable Gene L. Dodaro
Comptroller General
U.S. Government Accountability Office
441 G Street NW
Washington DC, 20548

Dear Mr. Dodaro:

We are continuing to conduct oversight of government policies affecting drug prices in the United States. The Department of Health and Human Services (HHS) recently issued a proposal to modify how pharmaceutical benefit managers (PBMs) handle rebates within Medicare and Medicaid.¹ The proposed rule threatens to raise Medicare Part D premiums, leading the Centers for Medicare and Medicaid Services (CMS) to announce a “demonstration project” in which the government would assume 95 percent of insurance company losses caused by the rule.² These actions amount to using a demonstration project to finance a taxpayer-funded bailout—which Republicans rightly criticized when HHS attempted it during the Obama Administration.³

In February 2019, HHS and its Office of Inspector General (OIG) published a proposed rule to remove certain prescription drug rebates from the safe-harbor protection under the Anti-Kickback statute.⁴ Specifically, the rule would eliminate the safe harbor for rebates to insurers and PBMs for Medicare Part D prescription drugs and Medicaid managed care plans, but not private-employer-based insurance.⁵ Instead, HHS proposed a new safe harbor for discounts at the point-of-sale for beneficiaries, beginning in January 2020.⁶

CMS anticipates that the proposed rule will raise Medicare Part D premiums. The Office of the Actuary estimated that it would increase Part D premiums from between \$3.20 and \$5.64 per beneficiary per month in 2020.⁷ The Office of the Actuary also estimated that the proposed

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rule would increase total federal spending by \$196 billion from 2020 to 2029.⁸ Likewise, the Congressional Budget Office (CBO) estimated the proposed rule would cost \$177 billion over the next decade.⁹

On April 5, 2019, CMS Administrator Seema Verma announced that CMS would conduct a two-year “demonstration project” if the proposed rule went into effect in 2020.¹⁰ Under the demonstration project, CMS guaranteed that the federal government “would bear or retain 95% of the deviation between the target amount . . . and the actual incurred costs . . . beyond the first 0.5%” in 2020.¹¹ In other words, federal taxpayers would assume the risk of insurance company losses caused by the proposed rule. CBO estimated that this project—which it dubbed a “loss-absorption program”—would increase federal spending by \$10 billion.¹²

This is not the first time that HHS has sought to use a demonstration project to finance a taxpayer-funded bailout. As signed into law, Obamacare mandated drastic cuts to the Medicare Advantage program, which allowed Medicare-eligible seniors to choose a private health plan.¹³ In 2010, CMS announced an \$8 billion demonstration project to subsidize the Medicare Advantage program through quality bonus payments.¹⁴ In a July 2012 letter to then-Secretary Kathleen Sebelius, the Government Accountability Office (GAO) raised concerns about the demonstration project and questioned HHS’s authority to initiate the project.¹⁵ This Committee conducted oversight of this bailout during the Obama Administration.¹⁶

I respectfully request that GAO evaluate CMS’s recently announced demonstration project to determine whether it is an appropriate use of its statutory authority. If you have any questions about this request, please contact Committee staff at (202) 225-5074. Thank you for your attention to this matter.

Sincerely,



Jim Jordan
Ranking Member

⁸ Centers for Medicare & Medicaid Servs., Off. of the Actuary, Memorandum on Proposed Safe Harbor Regulations (Aug. 30, 2018).

⁹ CONG. BUDGET OFF., INCORPORATING THE EFFECTS OF THE PROPOSED RULE ON SAFE HARBORS FOR PHARMACEUTICAL REBATES IN CBO’S BUDGET PROJECTIONS—SUPPLEMENTAL MATERIAL FOR UPDATED BUDGET PROJECTIONS: 2019 TO 2029 (2019).

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The Honorable Gene L. Dodaro

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Inspector General
Department of Health and Human Services
330 Independence Avenue S.W.
Washington DC, 20201

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This is not the first time that HHS has sought to use a demonstration project to finance a taxpayer-funded bailout. As signed into law, Obamacare mandated drastic cuts to the Medicare Advantage program, which allowed Medicare-eligible seniors to choose a private health plan.¹³ In 2010, CMS announced an \$8 billion demonstration project to subsidize the Medicare Advantage program through quality bonus payments.¹⁴ In a July 2012 letter to then-Secretary Kathleen Sebelius, the Government Accountability Office (GAO) raised concerns about the demonstration project and questioned HHS’s authority to initiate the project.¹⁵ This Committee conducted oversight of this bailout during the Obama Administration.¹⁶

To assist the Committee in evaluating the proposed rule and the loss-absorption program, I respectfully ask that you provide the following documents as soon as possible but no later than June 6, 2019:

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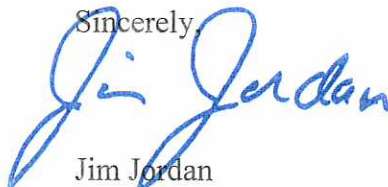
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The Honorable Daniel R. Levinson
May 23, 2019
Page 3

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Sincerely,

A handwritten signature in blue ink that reads "Jim Jordan". The signature is written in a cursive style with a large, stylized "J" and "D".

Jim Jordan
Ranking Member

cc: The Honorable Elijah E. Cummings, Chairman

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May 23, 2019

The Honorable Russ Vought
Acting Director
Office of Management and Budget
725 17th Street NW
Washington DC, 20503

Dear Acting Director Vought:

We are continuing to conduct oversight of government policies affecting drug prices in the United States. The Department of Health and Human Services (HHS) recently issued a proposal to modify how pharmaceutical benefit managers (PBMs) handle rebates within Medicare and Medicaid.¹ The proposed rule threatens to raise Medicare Part D premiums, leading the Centers for Medicare and Medicaid Services (CMS) to announce a “demonstration project” in which the government would assume 95 percent of insurance company losses caused by the rule.² These actions amount to using a demonstration project to finance a taxpayer-funded bailout—which Republicans rightly criticized when HHS attempted it during the Obama Administration.³

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The Honorable Russ Vought
May 23, 2019
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I respectfully urge you to scrutinize these proposals to ensure that they comply with federal law and regulation and minimize costs to taxpayers.

If you have any questions about this request, please contact Committee staff at (202) 225-5074. Thank you for your attention to this matter.

Sincerely,

Jim Jordan
Ranking Member

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The Honorable Russ Vought

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