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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL
JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

September 11, 2019

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

As U.S. Senators serving on the Committee on Finance, which has the responsibility for overseeing the Medicare program, we urge the Department of Health and Human Services (HHS) to use its regulatory authority to reform direct and indirect remuneration (DIR) with respect to pharmacies under the Medicare Part D program. Specifically, we ask HHS to revive the pharmacy DIR reforms included in the Centers for Medicare and Medicaid Services (CMS) November 30, 2018 proposed rule, “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,” (CMS-4180-P), and finalize them for plan year 2021. These reforms will provide needed financial relief to pharmacies and beneficiaries.

CMS documented an extraordinary 45,000 percent increase in DIR fees paid by pharmacies from 2010 to 2017. This is an untenable trend for pharmacies and causes higher prices for beneficiaries at the pharmacy counter. Moving forward with the proposed reforms, we urge the agency to redefine “negotiated price” to include all pharmacy price concessions at the point-of-sale and establish a broader definition of “price concession” to bring clarity to the true price Medicare pays for a Part D drug and provide financial relief to beneficiaries, many of whom struggle to afford their medications. When finalized, the changes will help preserve beneficiary

access to community pharmacies and lower out-of-pocket costs – both of which will improve prescription drug adherence and health outcomes.

We urge swift reform because we remain highly concerned about a Part D plan and Pharmacy Benefit Manager (PBM) practice of applying DIR fees through a “clawback” of payments made after the point-of-sale. The retroactive extraction of such fees is straining the viability of pharmacy operations. Pharmacy closures harm our communities and have adverse health consequences for patients. A 2019 study found that older adults filling prescriptions for statins, beta blockers, or oral anticoagulants at pharmacies that closed experienced an immediate statistically and clinically significant decline in medication adherence during the first three months after closure. The adverse impact persisted over 12 months and was greater among older adults living in neighborhoods with fewer pharmacies.¹

Pharmacy DIR reforms will lower the amount beneficiaries pay out-of-pocket at the pharmacy counter. Such changes that reduce patient drug costs also increase medication adherence and reduce overall health care costs. A 2019 study found that Medicare could save \$13.7 billion in annual health care costs if 25 percent of non-adherent beneficiaries with hypertension became medication compliant. These savings would result from reduced emergency department visits and inpatient stays.²

CMS’ estimate of the impact of its November 30, 2018 proposed rule recognized the direct benefit of DIR reform to beneficiaries, estimating a decrease in cost-sharing of between \$7.1 and \$9.2 billion over a ten-year period. While CMS estimated that these reforms could increase government spending due to an increase in premiums, it appears to have failed to account for savings from improved medication adherence and behavioral changes by Part D plans and PBMs that would continue to seek to keep premiums low. An analysis of a 2017 CMS Request for Information on a broader proposal that included pharmacy DIR reforms conducted by the consulting firm Milliman found that “the net impact of potential behavioral changes could be to reduce spending for all stakeholders, with overall government savings of \$8 to \$73 billion over ten years.”³ We urge HHS to reassess the impact of pharmacy DIR reforms using a more robust analysis that includes these factors during the regulatory process.

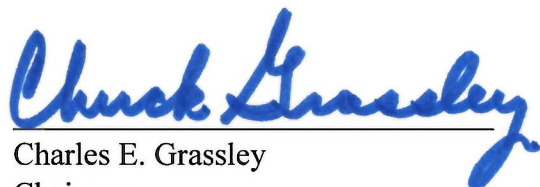
In conclusion, we urge HHS to use its regulatory authority to reform pharmacy DIR for plan year 2021 by reviving and finalizing the changes proposed in November 2018. These reforms, along with movement to a standardized set of pharmacy quality metrics, will enable pharmacies to best serve beneficiaries and bring more transparency and value to the Part D program.

¹ Qato, DM, et, al. “Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults.” JAMA. April 19, 2019.

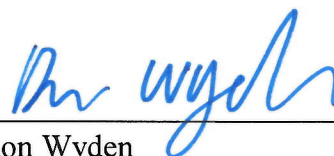
² Lloyd, Jennifer, et, al. “How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program?” Medical Care. January 2019.

³ Milliman. “Reducing Part D Beneficiary Costs Through Point of Sale Rebates”. Client Report. January 16, 2018.

Sincerely,



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U.S. Senate Committee on Finance



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U.S. Senate Committee on Finance




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Senator
U.S. Senate Committee on Finance



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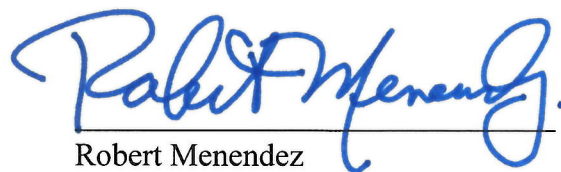
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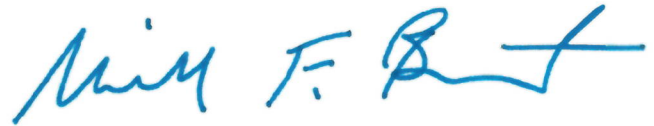
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Senator
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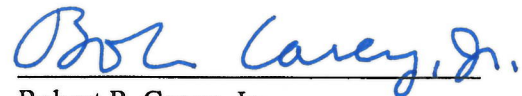
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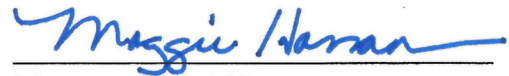
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Margaret Wood Hassan
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Catherine Cortez Masto
Senator
U.S. Senate Committee on Finance

Cc: The Honorable Russell Vought, Acting Director, Office of Management and Budget