Congress of the United States
Washington, DC 20515

January 26, 2018

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

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Secretary Azar and Administrator Verma:

We write today in response to the proposed rule updating Medicare Advantage (MA) and the Prescription Drug Benefit Program (Part D) for Contract Year 2019 (CMS-4182-P) released on November 16, 2017. In 2003, a Republican-controlled Congress passed and President George W. Bush signed into law the Medicare Prescription Drug, Improvement and Modernization (MMA) Act which produced the largest overhaul of Medicare in the program's 38-year history. The MMA not only contained much needed reforms that brought us the competitive Medicare Advantage (MA) program that we know today, but it also created the voluntary, private sector based, prescription drug program known as Part D. We appreciate this Administration's focus on modernizing and improving both of these programs through numerous proposals contained in the proposed rule and we look forward to working with you to continue the good work that has begun. Specifically, as changes to the Medicare Part D program are considered, we want to ensure the Administration takes a balanced approach to lowering beneficiaries' out-of pocket costs while also preserving the intent of the "noninterference clause."

The noninterference clause strictly prohibits the federal government from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and PDP sponsors."[1] This was done intentionally to allow the private sector to compete to provide the best value for the program.

The Part D program relies on sponsors to negotiate drug manufacturer rebates and other price concessions to reduce the cost of the program to beneficiaries and the government. As you consider program changes, including through the Request for Information (RFI), it is critical that the Secretary ensures that private business negotiations continue to be protected by the noninterference clause.

[1] 42 U.S.C. § 1395w-111(i)(1)ld

In addition to protecting the intent of the noninterference clause, we would encourage the Administration to carefully review the impact of the proposed policy in the RFI, and ensure that any changes:

(1) not be administratively difficult for both CMS, plans, manufacturers and pharmacies to implement;
(2) not result in the disclosure of competitively sensitive information, especially in drug classes that have two or fewer rebated drugs;
(3) meaningfully reduce program costs for beneficiaries, especially those seniors hit hardest by high cost drugs, and the taxpayer.

Under current law, all DIR and pharmacy price concessions, including the portion that the Pharmacy Benefit Manager (PBM) retains, are required to be reported to CMS. After the close of the plan year, sponsors are required to provide CMS with information about the actual amount of DIR and pharmacy price concessions they received through a process known as reconciliation. The reconciliation process is used to verify whether or not the federal government has overpaid or underpaid the plan.[2] The federal government recoups or pays plans more based on this information. It is CMS' responsibility to ensure that proper controls are in place to detect inaccuracies in the sponsors' rebate reports and that their systems do not have any vulnerabilities that could result in inaccuracies. As such, we implore the Administration, prior to officially proposing any type of mandated pass through at the point of sale, to fully review the DIR and pharmacy price concessions information that is already required to be reported to CMS by the plan sponsors to ensure that all DIR and pharmacy price concessions are being passed through to the Medicare program.

We share the concern pointed out by the Administration that a beneficiary could be paying more at the counter since beneficiaries sometimes pay a coinsurance on the gross cost of a drug to the plan, rather than the rebated amount to the plan. We believe the RFI—being an opportunity for all stakeholders to offer ideas and solutions – opens an important discussion, with the ultimate goal of reducing prescription drug costs for all beneficiaries. Rather than mandating a certain percentage of DIR and pharmacy price concessions be passed through at the point of sale, the Administration may be interested in other alternatives, such as, but not limited to, creating a reconciliation process for beneficiary overpayments, similar to that of the federal government, at the end of the year, and ensuring all DIR and pharmacy price concessions are passed through to the Medicare program at the end of the year.

As members of the Committees with jurisdiction over the Medicare Part D program, we urge the Admnistration's continued support and protection of the Part D program as well as carefull consideration of precedent setting policies and alternative approaches that successfully address these challeneges.

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[2] 42 CFR §§ 423.315 and 423.343.

Sincerely,

Peter J. Roskam
Chairman
Health Subcommittee on Ways and Means
U.S. House of Representatives

Bill Johnson
Committee on Energy and Commerce
U.S. House of Representatives

Sam Johnson
Health Subcommittee on Ways and Means
U.S. House of Representatives

Erik Paulsen
Health Subcommittee on Ways and Means
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Jim Renacci
Committee on Ways and Means
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Tim Walberg
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