Congress of the United States
Washington, DC 20510

August 9, 2018

The Honorable Mick Mulvaney
Director
Office of Management and Budget
Executive Office of the President
The White House
Washington, DC 20500

Dear Director Mulvaney:

We applaud the key role that you have played in President Trump's Administration on developing policies that aim to lower prescription drug costs for the many individuals and families who struggle to afford needed medications. These efforts include the development of the Administration's *American Patients First* blueprint, a Request for Information (RFI) on policy change options included in a November 2017 proposed rule to update the Part D program, and the President's FY 2019 budget submission to Congress.

Most recently, you and your office have been tasked with reviewing the proposed rule, "Removal Of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection" submitted by the Department of Health and Human Services (HHS)/Office of Inspector General (OIG) on July 18, 2018.[1] While the details of the proposed rule are unavailable during the period of review, the publicly available title of the rule indicates that the action contemplated could be significant in scope, with the potential to dramatically change the process by which prescription drugs are purchased within the supply chain. Depending on the nature of the policies contemplated, possible changes could ripple across the health care sector, altering a major sector of the U.S. economy that Americans depend upon for their health and well-being. As such, we ask that you ensure that the proposed rule include a robust regulatory impact analysis prior to clearing it for publication.

As you know, Executive Order 12866 requires that detailed assessment and quantification of likely costs and benefits, as well as similar analysis of reasonable alternatives, be included in a proposed rule that is of economic significance. The initial posting of the notice of the HHS/OIG proposed rule submission on the OMB Office of Information and Regulatory Affairs (OIRA) website stated that the pending proposal was not economically significant. While that notation was updated on July 19, 2018 to indicate the proposed rule is economically significant, the possibility that such designation was in question as HHS/OIG submitted it to OMB is concerning. A robust analysis of how the proposal is expected to change the interactions between drug manufacturers and insurers, or those who negotiate on their behalf, and the impact on patients and all federal health programs supported by taxpayers is needed to inform public comment.

Irrespective of the support, concerns, and questions that result from this proposed rule, removing safe harbor protections for rebates used to purchase prescription drugs would alter any federal, taxpayer-financed program to which it applies, changing regulations and practices that have been acceptable for decades. It likely also interacts with antitrust and other statutory provisions that have their own corresponding regulations. It is for these reasons that a transparent, open, and deliberative process that allows for significant Congressional and stakeholder input is paramount.

We appreciate your commitment to ensuring that consideration is given to the HHS/OIG proposed rule currently before OMB for review so that it is clear that any eventual change is in the best interest of patients, the federal programs that provide care for them, and the taxpayers who support them.

Sincerely,

Orrin Hatch
Chairman
Senate Committee on Finance

Greg Walden
Chairman
House Committee on Energy and Commerce