United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

September 20, 2016

The Honorable Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services
Office of the Inspector General
330 Independence Avenue SW
Washington, DC 20201

Dear Inspector General Levinson:

As Members of the Senate Finance Committee (Committee), we have a responsibility to ensure the effectiveness and solvency of the Medicaid program. To that end, we, along with numerous of our colleagues in the Senate and House of Representatives, are concerned with recent reports about the potential manipulation of the Medicaid Drug Rebate Program (MDRP) and whether or not the Centers for Medicare & Medicaid Services (CMS) is conducting sufficient oversight on this issue.

The Medicaid program spent $42.7 billion in brand and generic drugs and received $19.9 million in manufacturer rebates in fiscal year 2014.[1] Manufacturer rebates play an important role in helping to offset the ever-increasing costs of prescription drug to the Medicaid program. The recent controversy surrounding Mylan's prescription drug product EpiPen® raises questions about the controls in place to ensure that drug manufacturers are paying appropriate rebates. The categorization of prescription drugs as generics instead of branded drugs has real financial impacts on the MDRP.

[1] Medicaid and CHIP Payment and Access Commission (MACPAC), "Medicaid Gross Spending and Rebates for Drugs by Delivery System." Available at https://www.macpac.gov/publication/medicaid-gross-spending-and-rebates-for-drugs-by-delivery-system/. MACPAC notes that the "Due to the time it takes to collect the drug utilization information and invoice drug manufacturers for the rebate, the rebates collected in any particular quarter are generally attributable to drugs purchased in prior quarters; thus, the gross spending and rebate dollars for a given time period are not necessarily aligned."

The National Association of Medicaid Directors (NAMD) recently raised their concerns on this issue in a memo to Congress where they wrote, "if EpiPen is considered a generic for Medicaid rebate purposes but is not an actual generic product, it appears Mylan is taking advantage of the MDRP."[2] NAMD went on to state that "[t]he classification of EpiPen (both the device and the drug administered through it) as a generic drug under the MDRP means the inflation protections applicable to brand drugs have not protected Medicaid programs from Mylan's price increases over the years, and Medicaid programs have been subjected to the same increases in Average Wholesale Price (AWP) as commercial insurers and consumers."[3]

The MDRP ensures that pharmaceutical manufacturers pay states a rebate off of the AMP. The percentage pharmaceutical manufacturers pay Medicaid is higher for brand drugs (23.1 percent) compared to generic drugs (13 percent), thus, Medicaid receives a lower rebate for drugs inappropriately categorized as generics.

Additionally, the MDRP has helped limit the effect of sharp increases in the prices of brand drugs on Medicaid for years by requiring pharmaceutical manufacturers to pay additional rebates if the costs of the brand drugs rises more than inflation. No such provision existed for generic drugs prior to the 2015 Bipartisan Budget Act.[4] As a result, misclassifying a brand drug as a generic insulated the manufacturer from paying Medicaid additional rebates when it increased the price of drugs. Finally, another provision in the MDRP requires manufacturers to offer state Medicaid programs the lowest price it offers to other payers, with some exceptions.

Pharmaceutical manufacturers, including Mylan, have previously been subject to enforcement action for misclassifying brand drugs as generic drugs. Mylan was one of four companies that in October 2009 entered into settlement agreements for a total of $124 million to resolve claims that they violated the False Claims Act by failing to pay appropriate rebates to state Medicaid programs for drugs paid for by those programs.[5]

Given the concerns raised by NAMD and the past behavior in this area, we are concerned that the controls in place, if any, are inadequate to ensure that Medicaid is receiving the full amount of rebates afforded to it by law. Therefore, we write to you today to join our Republican colleagues from the House Energy & Commerce Committee in their September 12, 2016, request that the Office of the Inspector General examine CMS's oversight of the MDRP.

The Medicaid program is a vital part of our healthcare system and its financial viability is a critical area of concern for this Committee. A thorough and timely review of these issues by the Office of the Inspector General will provide important information to Congress about how CMS

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[2] National Association of Medical Directors, Memo to Congressional staff regarding "Impact of EpiPen Price Increases on the Medicaid Program." September 8, 2016.

[3] Id.

[4] Bipartisan Budget Act of 2015, P.L. 114-74.

[5] Department of Justice, "Four Pharmaceutical Companies Pay $124 Million for Submission of False Claims to Medicaid." October 19, 2009. Available at https://www.justice.gov/opa/pr/four-pharmaceutical-companies-pay-124-million-submission-false-claims-medicaid

is overseeing this significant part of the Medicaid program and where changes in policy need to be made to protect the program against these types of vulnerabilities in the future.

Sincerely,

Orrin G. Hatch
Chairman

Chuck Grassley
United States Senator

Mike Crapo
United States Senator

Pat Roberts
United States Senator

Michael B. Enzi
United States Senator

John Cornyn
United States Senator

John Thune
United States Senator

Richard Burr
United States Senator

Johnny Isakson
United States Senator

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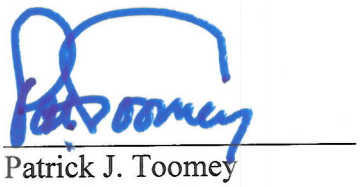
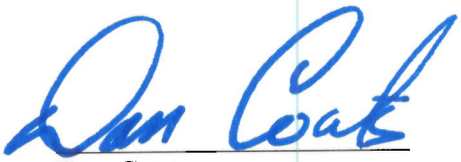
United States Senator



Patrick J. Toomey
United States Senator



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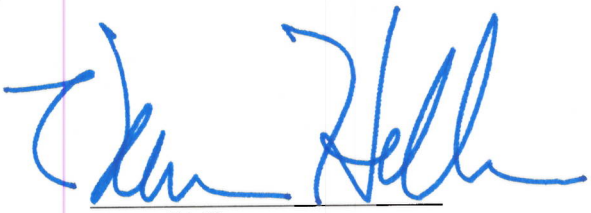
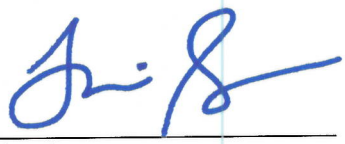
United States Senator



Dean Heller
United States Senator



Tim Scott
United States Senator