

Congress of the United States

Washington, DC 20510

September 2, 2016

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

As Ranking Members of the relevant committees of jurisdiction, we have the privilege and responsibility of overseeing the Medicaid and Children's Health Insurance (CHIP) programs. Today, Medicaid and CHIP provide coverage to more than 72 million individuals, including more than 35 million children. Unfortunately, when it comes to spending, Medicaid has not been exempt from national trends in the rise of prescription drugs. In 2014, net drug spending in Medicaid was \$22 billion—a 24.3 percent increase from the previous year.¹

In early August, a number of reports highlighted the sudden spike in the price of the EpiPen®—a brand name product most commonly purchased and prescribed to administer epinephrine, an injectable stimulant (also known as adrenaline) used to halt the symptoms of a severe allergic reaction. According to reports, an estimated 3.6 million people in the United States were prescribed an EpiPen® in 2015 alone.² Reports have also found that since 2007, when the pharmaceutical company Mylan acquired the product, the list price for a package of two EpiPen® Auto-Injectors has increased from just over \$100 to more than \$600.³

To help tackle the cost of prescription drugs for the nation's largest safety net, Congress created the Medicaid Drug Rebate Program in 1990 as part of the Omnibus Budget Reconciliation Act.⁴ Under the Medicaid Drug Rebate Program, pharmaceutical companies like Mylan are responsible for accurately reporting and paying a rebate on drugs paid for by Medicaid, including products such as the EpiPen®.

Under current law, branded drugs and authorized generic drugs (i.e., single source and innovator multiple source drugs) are required to pay a basic rebate amount that consists of the greater of

¹ MACPAC, ISSUE BRIEF, MEDICAID SPENDING FOR PRESCRIPTION DRUGS (Jan. 2016), *available at* <https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf>.

² Jonathan D. Rockoff, *Mylan Faces Scrutiny Over EpiPen Price Increases*, WALL STREET JOURNAL, Aug. 24, 2016, *available at* <http://www.wsj.com/articles/mylan-faces-scrutiny-over-epipen-price-increases-1472074823>.

³ Andrew Pollack, *Mylan Raised EpiPen's Price Before the Expected Arrival of a Generic*, N.Y. TIMES, Aug 24, 2016, *available at* http://www.nytimes.com/2016/08/25/business/mylan-raised-epipens-price-before-the-expected-arrival-of-a-generic.html?_r=0.

⁴ Omnibus Budget Reconciliation Act of 1990, P.L. 101-508 (1990).

either 23.1 percent of the Average Manufacturer Price (AMP) or AMP minus the “best price,”⁵ where best price is statutorily defined as the lowest price available to any wholesaler, retailer, provider, or paying entity excluding certain governmental payers.⁶ As part of the Affordable Care Act, this drug class is also subject to an additional inflationary rebate that applies when an increase in a drug’s AMP rises faster than inflation. Generic drugs, also known as non-innovator multiple source drugs, are subject to a much lower rebate under the Medicaid Drug Rebate Program of 13 percent of AMP. Generic drugs have also traditionally been exempt from the additional inflationary rebate obligation; however, this will change starting next year.⁷

While the EpiPen® is considered a branded drug listed under a New Drug Application (NDA) by the Food and Drug Administration (FDA), it has recently come to our attention that Mylan has classified the EpiPen® as a generic drug (*i.e.*, non-innovator multiple source drug) for purposes of the Medicaid Drug Rebate Program.

We understand that in a 1997 letter from the U.S. Department of Health & Human Services to Dey Laboratories, Inc (a specialty pharmaceutical business acquired by Mylan in 2007, now known as Mylan Specialty⁸), a health insurance specialist, potentially responding to an inquiry, wrote that “even though the current NDCs of these products . . . are listed under an NDA, it is entirely fitting and proper for you to report them to the Drug Rebate Program with a Drug Category of “N” (Non-innovator, Multiple Source) and be subject to the lowest rebate amount”⁹ However, this is inconsistent with how the FDA lists the EpiPen®,¹⁰ as well as how Medicare treats these products for purposes of the Medicare Part D prescription drug program. As a result, over the past two decades, it appears that Medicaid may have been grossly overpaying for EpiPen® and its related products due to Mylan’s misclassification. It appears that rather than paying the 23.1 percent rebate for a branded drug, Mylan has been paying the much lower generic rebate of 13 percent. Furthermore, it also appears that due to this practice, Mylan has effectively been exempt from any inflationary rebate obligations—particularly striking given the 480 percent list price increase of the EpiPen® since 2007.¹¹

As we review this issue, we respectfully request your timely response to the following questions:

1. Is Mylan currently in compliance with the requirements of the Medicaid Drug Rebate Program?

⁵ MEDICAID.GOV, MEDICAID DRUG REBATE PROGRAM, *available at* <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/medicaid-drug-rebate-program.html> (last visited Sept. 1, 2016).

⁶ Social Security Act §1927(c)(1)(C).

⁷ Bipartisan Budget Act of 2015, P.L. 114-74

⁸ Mylan Inc., *Mylan to Change Name of Specialty Subsidiary From Dey Pharma to Mylan Specialty*, PR NEWSWIRE, Feb. 15, 2012, *available at* <http://www.prnewswire.com/news-releases/mylan-to-change-name-of-specialty-subsidiary-from-dey-pharma-to-mylan-specialty-139349463.html>.

⁹ Letter from the U.S. Department of Health & Man Services, Health Care Financing Administration, to Dey Laboratories, Inc. (Oct. 23, 1997), *available at* <https://www.politicopro.com/health-care/story/2016/09/epipen-paid-generic-drug-prices-to-medicaid-while-profiting-from-brand-drug-protections-128200>.

¹⁰ FDA, DRUGS@FDA, *available at* <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm> (listed visit Sept. 1, 2016).

¹¹ *Rising cost of potentially life-saving EpiPen puts pinch on families*, CBS NEWS, Aug. 16, 2016, *available at* <http://www.cbsnews.com/news/allergy-medication-epipen-epinephrine-rising-costs-impact-on-families/>.

2. What are the current classification and rebate obligations under the Medicaid Drug Rebate Program for Mylan's EpiPen® Auto-Injectors?
3. What additional communications, if any, have been made before or since the 1997 letter to Dey Laboratories, Inc.¹² or Mylan regarding Medicaid drug rebate obligations for Mylan's EpiPen® or related branded products?
4. To what extent has the Medicaid Covered Outpatient Drug final rule released on January 21, 2016 impacted Mylan's rebate obligations under the Medicaid Drug Rebate Program?¹³
5. Since its original approval in 1987, how has the EpiPen® been classified by relevant pharmaceutical companies since the creation of the Medicaid Drug Rebate Program?
6. How much have state and federal governments lost in rebate revenue under the Medicaid Drug Rebate Program as a result of Mylan's classification of the EpiPen® and related products as generic drugs (*i.e.*, non-innovator multiple source drugs) for purposes of the Medicaid Drug Rebate Program?
7. Are there other Mylan branded and/or authorized generic products approved under NDAs that have been or are currently classified as generic drugs (*i.e.*, non-innovator multiple source drugs) under the Medicaid Drug Rebate Program?
8. Has the Centers for Medicare & Medicaid Services (CMS) reviewed the status of Mylan's classification of the EpiPen® and related products for purposes of the Medicaid Drug Rebate Program at any point, and if so, when?
9. Once it has become apparent that a rebate has been misclassified, what is the process by which the misclassification is corrected and the Medicaid program is paid accurately?

When Congress created the Medicaid Drug Rebate Program, it was with the intent of ensuring that the federal program responsible for providing health coverage to millions of our most

¹² See *supra* note 9.

¹³ Medicaid Program; Covered Outpatient Drugs, available at <https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf>.

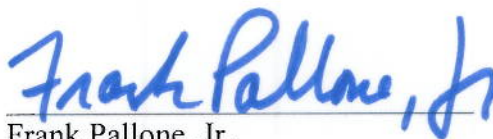
vulnerable populations always received the best possible price for prescription drugs. That intent must be realized to the fullest extent.

Thank you for your prompt attention to this matter.

Sincerely,



Ron Wyden
Ranking Member
Senate Finance Committee



Frank Pallone, Jr.
Ranking Member
House Energy & Commerce Committee

cc: Andrew M. Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services
cc: Victoria Wachino, Director, CMS Center for Medicaid and CHIP Services