

# Congress of the United States

Washington, DC 20515

December 9, 2016

Mr. Andy Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Acting Administrator Slavitt:

The House Committee on Energy and Commerce and Senate Committee on Finance are conducting oversight of the misclassification of the EpiPen® Auto-Injector and EpiPen Jr® Auto-Injector (collectively, "EpiPen") by Mylan Pharmaceuticals. On October 7, 2016, Mylan announced it agreed to the terms of a \$465 million settlement with the U.S. Department of Justice (DOJ) and other government agencies related to the classification of EpiPen for purposes of the Medicaid Drug Rebate Program.<sup>1</sup>

During the Clinton Administration in 1997, the EpiPen was classified as a non-innovator, or generic drug, for purposes of the Medicaid Drug Rebate Program. Under the Medicaid Drug Rebate Program, this qualifies Mylan to pay a lower rebate, at 13 percent of the average manufacture price, instead of the rebate for brand name drugs, which is at 23.1 percent.<sup>2</sup> The EpiPen, however, is a brand drug because it has patent protection and has no Food and Drug Administration (FDA)-approved therapeutic equivalents. In fact, prior to 1997, the EpiPen was correctly classified as a brand drug.<sup>3</sup>

The Energy and Commerce Committee first raised concerns with EpiPen's classification under the Medicaid Drug Rebate Program in July 2015, and asked the Centers for Medicare & Medicaid Services (CMS) for information about the classification of the EpiPen in hearing questions for the record. Specifically, the Committee noted that "concerns have been raised to CMS that the manufacturer of EpiPen ... inappropriately classifies their products as generic drugs for purposes of Medicaid drug rebate, resulting in significantly lower Medicaid rebate obligations and potentially reduced patient access to other epinephrine auto-injectors subjected to

---

<sup>1</sup> Mylan website news release, <http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector> (last visited Oct. 31, 2016).

<sup>2</sup> Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program*, available at <https://www.medicare.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/medicaid-drug-rebate-program.html> (last visited Oct. 7, 2016).

<sup>3</sup> Letter to U.S. Senator Wyden from Andrew Slavitt, Centers for Medicare and Medicaid Services Acting Administrator, October 5, 2016.

higher brand drug rebates.”<sup>4</sup> The Committee asked for information about CMS’ actions in response to these concerns.

In February 2016, CMS informed the Energy and Commerce Committee that “it is the manufacturers’ responsibility to ensure that the information about its drug products is reported accurately to the Medicaid Drug Rebate Program.” CMS explained that “if CMS identifies any misreporting in the product data reported by the manufacturer, CMS contacts the manufacturer to provide further guidance on how we recommend they correct the information being reported.” Regarding the specific concern over the misclassification of EpiPen, CMS reported the agency was “currently looking into the issue”, but did not answer the Committee’s specific questions or provide a timeframe for resolving concerns.<sup>5</sup> It is notable that CMS failed at that time to provide any specific details regarding its general oversight of manufacturers’ self-reported classification of drugs for purposes of the Medicaid Drug Rebate Program.

Recently, in a letter to Senator Wyden and Rep. Pallone on October 5, 2016, CMS revealed that Mylan had inappropriately classified the EpiPen as a generic drug. In the letter, CMS noted that it had “provided guidance to the industry and Mylan on the proper classification of drugs and has expressly told Mylan that the product is incorrectly classified.”<sup>6</sup> CMS also said that the incorrect classification has “financial consequences for the amount that federal and state governments spend because it reduces the amount of quarterly rebates Mylan owes to EpiPen.”<sup>7</sup> It appears that Mylan should have paid millions more dollars in rebates to the Federal Government through the Medicaid Drug Rebate Program.

Both Committees are concerned that CMS knew that EpiPen was misclassified for years and failed to take remedial action. As a result, on September 12, 2016, the Energy and Commerce Committee wrote to the Department of Health and Human Services Office of Inspector General (OIG) to request an investigation into CMS’ oversight of the Medicaid Rebate Program.<sup>8</sup> This request was echoed by the Senate Committee on Finance in a September 20,

---

<sup>4</sup> Letter from Joseph Pitts, Chairman, Subcomm. On Health, Energy & Commerce Comm., to Victoria Wachino, Director, Center for Medicaid & CHIP Services, July 28, 2015, *available at* <http://docs.house.gov/meetings/IF/IF14/20150708/103717/HHRG-114-IF14-Wstate-WachinoV-20150708-SD003.pdf>.

<sup>5</sup> Responses to Questions for the Record from Director for the Center for Medicaid and CHIP Services Vikki Wachino for the hearing, “Medicaid at 50” before the Energy and Commerce Committee’s Health Subcommittee held on July 8, 2015, *available at* <http://docs.house.gov/meetings/IF/IF14/20150708/103717/HHRG-114-IF14-Wstate-WachinoV-20150708-SD002.pdf>.

<sup>6</sup> Letter from Sen. Wyden and Rep. Pallone to Sylvia Burwell, Secretary, Dept. of Health & Human Services, Sept. 2, 2016, *available at* <http://www.finance.senate.gov/imo/media/doc/Wyden%20EpiPen%20Medicaid%20Letter%20from%20CMS%2010.5.16.pdf>.

<sup>7</sup> *Id.*

<sup>8</sup> Letter from Fred Upton, Chairman, Energy & Commerce Committee to Daniel Levinson, Inspector General of the Dept. of Health & Human Services, Sept. 12, 2016, *available at* <https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/114/letters/20160912HHS.pdf>.

2016, letter to the OIG.<sup>9</sup> Given the seriousness of this violation and its bearing on the integrity of the Medicaid Drug Rebate Program, the Committee also requests that CMS address these issues immediately by providing the following additional information and documents to the Committees by December 20, 2016.

1. CMS is on record saying that “The Center for Medicaid and CHIP Services in CMS has, on multiple occasions, provided guidance to the industry and Mylan on the proper classification of drugs and has expressly told Mylan that the product is incorrectly classified.”<sup>10</sup>
  - a. When did CMS staff first discover that Mylan Pharmaceutical’s classification of the EpiPen as a generic drug was incorrect?
  - b. When CMS staff became aware the classification was incorrect, what steps did they take to notify CMS leadership? Please provide a list of the personnel involved and timeline of actions taken.
  - c. On what dates did CMS notify Mylan Pharmaceuticals about the misclassification of the EpiPen? Please provide a list of the dates of each communication with employees of Mylan regarding the classification of the EpiPen, including meetings, phone calls, letters and emails. Include the names of the individuals at CMS and Mylan involved in the communication and describe the communication.
  - d. When CMS informed Mylan that EpiPen was misclassified under the Medicaid Drug Rebate Program, what date of compliance did CMS identify by which Mylan must act in accordance with program requirements and what direction did CMS provide to Mylan Pharmaceuticals regarding other actions the company should take, including refunding owed rebates to Federal and State governments?
  - e. How is EpiPen classified as of today? In CMS’ view, is it the proper classification? Please explain.
2. CMS Center for Medicaid and CHIP Services Director Vikki Wachino noted in answers to questions submitted for the record that “if CMS identifies any misreporting in the product data reported by the manufacturer, CMS contacts the manufacturer to provide further guidance on how we recommend they correct the information being reported.” Then, “if the manufacturer does not correct the issue in its reporting, CMS can, along with the Department of Justice (DOJ) and/or the Department of Health and Human Services (HHS) Office of Inspector General (OIG), take further action. As specified under section 1927(b)(3)(C)(ii) of the Act, a manufacturer that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for

---

<sup>9</sup> Letter from Chairman Hatch and Senate Finance Committee Republicans to Daniel Levinson, Inspector General of the Dept. of Health & Human Services, Sept. 20, 2016, available at <http://www.finance.senate.gov/chairmans-news/finance-republicans-call-for-review-of-rebate-practices-for-mylans-epipen>.

<sup>10</sup> Mylan website news release, <http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector> (last visited Oct. 31, 2016).

each item of false information, in addition to other penalties prescribed by law.”<sup>11</sup> Prior to July 2016, did any CMS staff discuss the possibility of working with DOJ or HHS OIG to explore the use of civil money penalty authorities?

3. In the Medicaid Program’s Covered Outpatient Drug Final Rule issued on February 1, 2016,<sup>12</sup> CMS noted there might be “very limited circumstances” where, “certain drugs” might be more appropriately classified for the purposes of the Medicaid Drug Rebate Program differently than their FDA approval status. In the Final Rule and the subsequent guidance, CMS specifically mentioned parenteral drugs in plastic immediate containers, for which FDA required that a new drug application (NDA) be filed, as a possible candidate for the Drug Category Narrow Exception. Since a parenteral drug product can refer to a sterile solution intended for administration by injection, this description would appear to include products such as EpiPen.

CMS has informed press and the Committee that it communicated to Mylan that EpiPen is misclassified. However, CMS has yet to explain precisely when Mylan must correctly classify EpiPen as a brand drug under the Medicaid Drug Rebate Program. Under CMS’s current guidance, “for drugs that are marketed under an NDA and are currently reported to the MDR program as non-innovator multiple source drugs, manufacturers will have four quarters after the effective date of the final rule, April 1, 2016, to submit materials to CMS demonstrating why the narrow exception should apply.”<sup>13</sup> Under this process, “if a manufacturer has previously reported a drug marketed under an NDA as a non-innovator multiple source drug, that manufacturer is responsible for submitting materials to demonstrate how its drug might be subject to the narrow exception to be classified as a non-innovator multiple source drug. CMS will review these materials and confirm in writing that the narrow exception does apply to the drug, or state that the narrow exception does not apply.”

- a. Has Mylan submitted documentation to CMS through the Drug Category Narrow Exception outlined in the May 2, 2016 guidance?
- b. If so, is CMS enforcing the guidance by implementing the correct classification of EpiPen (as a brand) after the Drug Category Narrow Exception process is exhausted, thus on or after April 1, 2016?

---

<sup>11</sup> Responses to Questions for the Record from Director for the Center for Medicaid and CHIP Services Vikki Wachino for the hearing, “Medicaid at 50” before the Energy and Commerce Committee’s Health Subcommittee held on July 8, 2015, *available at* <http://docs.house.gov/meetings/IF/IF14/20150708/103717/HHRG-114-IF14-Wstate-WachinoV-20150708-SD002.pdf>.

<sup>12</sup> Medicaid Program’s Covered Outpatient Drug final rule with comment (CMS-2345-FC) (“Final Rule”), 81 FR 5170 (Feb. 1, 2016) *available at* <https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf>. See page 5191.

<sup>13</sup> Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program Notice, Release No. 98, For Participating Drug Manufacturers, May 2, 2016, *available at* <https://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-098.pdf>.

- c. If so, why does CMS believe it is appropriate for a drug manufacturer to financially profit at the expense of the Medicaid Drug Rebate Program for a product that CMS acknowledges is wrongly classified?
4. If Mylan had properly classified EpiPen, how many more millions of dollars would the Medicaid program have saved since 1997?
  5. Through CMS's process to review comments on and finalize the Medicaid Program's Covered Outpatient Drug rule, did CMS learn of other drugs which may have been misclassified for purposes of the Medicaid Drug Rebate Program? If so, please provide the number of products and drug manufacturers which may be incorrectly classified at this time. Additionally, please describe what steps CMS is taking to remedy such misclassifications.
  6. CMS has said that it is a drug manufacturers' responsibility to ensure that the information about its drug products is reported accurately to the Medicaid Drug Rebate Program.<sup>14</sup> Does CMS take any steps to review or validate the accuracy or appropriateness of drug manufacturers' submissions of such information? Please describe the processes, policies, or personnel involved in any such review as of, and, separately, before July 2016.
  7. Did Mylan's misclassification of the EpiPen lead to covered entities participating in the 340B Drug Discount Program being effectively overcharged for EpiPens? Please explain.
  8. On November 7, 2016, CMS released a proposed notice with comment period announcing changes to the Medicaid National Drug Rebate Agreement (NDRA) for use by HHS and drug manufacturers under the Medicaid Drug Rebate Program.<sup>15</sup> The NDRA is used by HHS and drug manufacturers in the Medicaid Drug Rebate Program and includes provisions on the Secretary's and manufacturers' responsibilities under that program. Generally, in order for payment to be made under Medicaid for covered outpatient drugs, manufacturers must enter into an NDRA.
    - a. In the proposed notice, CMS said: "Once finalized, the updated NDRA would need to be signed by all participating manufacturers, as well as new manufacturers joining the program." However, CMS also noted that "manufacturers with an active NDRA at the time the updated NDRA is to be executed would not be subject to verification of their proposed covered outpatient drug list." Does this mean that CMS is effectively grandfathering some manufacturers' current NDRA's without reviewing the accuracy of their drug classifications? Please explain the policy effect and rationale.

---

<sup>14</sup> Responses to Questions for the Record from Director for the Center for Medicaid and CHIP Services Vikki Wachino for the hearing, "Medicaid at 50" before the Energy and Commerce Committee's Health Subcommittee held on July 8, 2015, *available at* <http://docs.house.gov/meetings/IF/IF14/20150708/103717/HHRG-114-IF14-Wstate-WachinoV-20150708-SD002.pdf>.

<sup>15</sup>Centers for Medicare and Medicaid Services, Proposed Notice Regarding Changes to the Medicaid Drug Rebate Program National Rebate Agreement, November 7, 2016, RIN-0938-ZB29, *available at* <https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-26834.pdf>.

- b. In the proposed notice, CMS noted it uses “drug information listed with FDA, such as Marketing Category and Drug Type, to be able to verify in some cases that an NDC meets the definition of a covered outpatient drug, therefore, manufacturers should ensure that their NDCs are electronically listed with FDA.” However, a 2010 review by the HHS OIG found that “sixty-two percent of drugs paid for by Medicaid in 2008 had an approved application number in the NDC Directory; the remaining 38 percent either did not have an approved application number listed or were not in the NDC Directory at all.”<sup>16</sup> So what does CMS propose to do for drugs State Medicaid programs currently cover which either do not have an approved application number listed or are not in the NDC Directory at all?

Any ongoing discussions between Mylan and DOJ should not impede CMS’s ability to answer the Committee’s questions about Mylan and CMS’ own management of the Medicaid Drug Rebate Program.

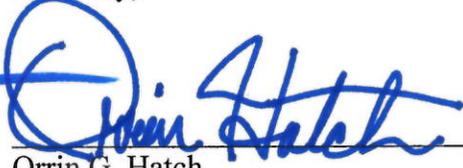
An attachment to this letter provides additional information about how to respond to the committee’s request. If you have any questions regarding this request, please contact Emily Felder or Josh Trent of the Committee on Energy and Commerce majority staff at (202) 225-2927, or Kim Brandt of the Committee on Finance majority staff at (202) 224-4515.

Sincerely,



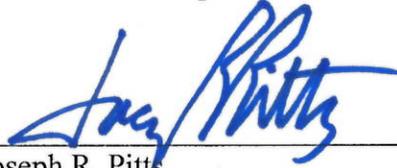
---

Fred Upton  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives



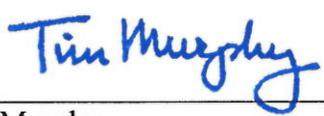
---

Orrin G. Hatch  
Chairman  
Committee on Finance  
U.S. Senate



---

Joseph R. Pitts  
Chairman  
Subcommittee on Health  
U.S. House of Representatives



---

Tim Murphy  
Chairman  
Subcommittee on Oversight and Investigations  
U.S. House of Representatives

---

<sup>16</sup> U.S. Department of Health and Human Services, Office Of Inspector General, *FDA’s Approval Status Of Drugs Paid For By Medicaid*, November 2010, OEI-03-08-00500, available at <https://oig.hhs.gov/oei/reports/oei-03-08-00500.pdf>.