

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

September 12, 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:

We write to you out of grave concern over recent reports noting that the Centers for Medicare and Medicaid (CMS) persistently allowed EpiPen® to be misclassified as a generic drug under the Medicaid rebate program, even though Mylan's EpiPen® is considered a brand drug.¹ CMS confirmed to our staff that the agency has informed Mylan the drug is misclassified.

We are especially troubled to learn that CMS has apparently been aware of this issue for years, but has apparently only recently taken remedial action after increased scrutiny from Congress and the media.² Given significant impact of drug coverage on Medicaid expenditures and Medicaid stakeholders, we respectfully request your office initiate an independent audit of CMS's oversight of the Medicaid Drug Rebate Program.³

Our concerns are particularly acute since our committee raised concerns over EpiPen's® classification with CMS officials more than a year ago. In hearing questions for the record in July 2015, we relayed that "concerns have been raised to CMS that the manufacturer of EpiPen®, epinephrine auto-injectors indicated for emergency treatment of anaphylaxis, inappropriately classifies their products as generic drugs for purposes of the Medicaid drug rebate, resulting in significantly lower Medicaid rebate obligations and potentially reduced patient access to other epinephrine auto-injectors subjected to higher brand drug rebates."⁴ At

¹ EpiPen® is considered a brand drug listed under a New Drug Application (NDA) by the FDA, but Mylan has classified the EpiPen® as a generic drug for purposes of the Medicaid Drug Rebate Program.

² Press reports include "CMS Tells Mylan It Incorrectly Classified EpiPen To Pay Lower Medicaid Rebates, Lawmakers Upset" on September 2, 2016 in *Inside Health Policy*, and "CMS Knew of EpiPen Misclassification Since at Least 2014," on September 2, 2016 in *POLITICO Pro*

³ <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/medicaid-drug-rebate-program.html>

⁴ <http://docs.house.gov/meetings/IF/IF14/20150708/103717/HHRG-114-IF14-Wstate-WachinoV-20150708-SD003.pdf>

that time, we asked whether or not CMS has looked into these concerns, inquired about the status of CMS's review and asked what, if any, actions CMS took or planned to take.

Despite multiple attempts to get answers from the agency, including sending a public letter months later reiterating our unanswered hearing questions,⁵ we did not receive written responses to our questions until February 2016—about seven months later. At that time, CMS declined to answer our specific question about EpiPen's® classification, instead merely saying the agency was “currently looking into the issue.”⁶

Like many of our colleagues in Congress, we are concerned that CMS's apparent failure to adequately oversee the Medicaid Drug Rebate Program to ensure the correct classification of EpiPen® had direct, negative financial consequences for State Medicaid programs. Lax oversight by CMS appears to have resulted in increased program expenditures since the drug manufacturer paid a lower Medicaid generic rebate instead of the higher brand rebate – the latter of which also may have included an additional rebate if prices rose faster than inflation. Several of our colleagues in Congress have already written to ask CMS to answer important questions about the impact of Mylan's price changes on health care entitlement programs⁷ and the financial impact of EpiPen's® misclassification on the Medicaid program.⁸ We will be very interested in CMS's response to many of these important and fair questions.

While we await a more fulsome explanation from CMS, it would be inadequate to merely rely on the agency to police itself and evaluate its effectiveness of its own oversight of EpiPen's® classification with the Medicaid drug rebate program. Therefore, in the interest of stewarding taxpayer dollars well and consistently enforcing clear program standards, we respectfully request the Office of the Inspector General (OIG) immediately open an independent inquiry examining CMS's oversight of the Medicaid Drug Rebate Program. We request that the OIG scope its evaluation to include – but not be limited to – the particulars of the EpiPen® concern. Specifically, we suggest the OIG consider the following questions in evaluating the agency's oversight of the Medicaid Drug Rebate Program:

1. **Are CMS staff consistently and effectively operationalizing CMS policy?** At the Centers for Medicaid and CHIP Services (CMCS) at CMS, what group of staff are primarily responsible for overseeing the Medicaid Drug Rebate Program? What, if any, training are these employees to receive training related to program management or implementation of policy standards? How does CMS ensure these employees are accurately and consistently enforcing existing CMS program rules? What, if any, training do these employees receive on drug pricing and the FDA classification of brand and generic drugs to consistently direct the program?
2. **Does CMS policy appropriately rely on FDA's classification?** A 1997 letter from HHS to Dey Laboratories (now Mylan Specialty) has been cited by some as HHS's approval for Mylan's classification of EpiPen®. However, as some have noted, this guidance

⁵ <https://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Letters/20160113CMS.pdf>

⁶ <http://docs.house.gov/meetings/IF/IF14/20150708/103717/HHRG-114-IF14-Wstate-WachinoV-20150708-SD003.pdf>

⁷ Multiple Senators, including Senators Ayotte and Grassley sent letters to CMS raising important questions.

https://www.ayotte.senate.gov/?p=press_release&id=2785 and <http://www.grassley.senate.gov/news/news-releases/senators-seek-information-epipen-price-increases-impact-medicare-medicaid>

⁸ <http://www.finance.senate.gov/imo/media/doc/Wyden%20Pallone%20EpiPen%20Medicaid%20Drug%20Rebate%20Letter-Sept%202.pdf>

appears to be inconsistent with how the FDA lists the product.⁹ If this dissonance is allowable, under what circumstances does CMS policy allow for the Medicaid rebate program to use a different drug classification than that used by the FDA? What if any guidance has been provided to drug manufacturers participating in the Medicaid Drug Rebate Program and how has that guidance changed in recent years?

3. **Does CMS have reasonable checks in place to evaluate manufacturer data?** Under section 1927 of the Social Security Act ("the Act"), drug manufacturers classify their drugs as either single-source drugs, innovator multiple-source drugs (both of which generally align with brand-name drugs), or non-innovator multiple-source drugs (which generally align with generic drugs) and report Average Manufacturer Price (AMP) and Best Price information to the Secretary for use in determining the manufacturer's rebate obligations. In the agency response to questions for the record, a Medicaid official explained "it is the manufacturers' responsibility to ensure that the information about its drug products is reported accurately to the Medicaid Drug Rebate program."¹⁰
 - a. If the responsibility for correct reporting lies with a drug manufacturer, what data systems, analytical tools, or other processes does CMS have to determine if drug manufactures are in compliance with the Medicaid Drug Rebate Program?
 - b. What, if any, system does CMS have in place for evaluating the accuracy of new or existing drug manufacturers' data, as submitted for participation in the Medicaid Drug Rebate Program?

4. **To what degree has CMS used existing authorities to enforce program policy over the past five years?** In CMS's response to questions for the record, a Medicaid official 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. 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 each item of false information, in addition to other penalties prescribed by law."¹¹
 - a. Over the past five years, how often have CMS staff identified any misreporting in the product data—including the drug classification, AMP, or best price—reported by the manufacturer and contacted the manufacturer to provide further corrective guidance? How was such misreporting in the product data identified and what, if any, corrective actions did CMS require from manufacturers?
 - b. Has CMS ever used the authority under section 1927(b)(3)(C)(ii) of the Act to levy civil monetary penalties on drug manufacturers who have been found to have knowingly provided false information to CMS?

5. **What is CMS doing to identify other situations similar to the EpiPen® case with the aim of appropriately protecting Medicaid expenditures?** Are there other branded and/or authorized generic products approved under new drug applications that have been

⁹ <http://www.finance.senate.gov/imo/media/doc/Wyden%20Pallone%20EpiPen%20Medicaid%20Drug%20Rebate%20Letter-Sept%202.pdf>

¹⁰ <http://docs.house.gov/meetings/IF/IF14/20150708/103717/HHRG-114-IF14-Wstate-WachinoV-20150708-SD002.pdf>

¹¹ <http://docs.house.gov/meetings/IF/IF14/20150708/103717/HHRG-114-IF14-Wstate-WachinoV-20150708-SD002.pdf>

classified as generic drugs under the Medicaid Drug Rebate Program? If so, what steps, if any, has CMS taken with respect to these products to consistently enforce program requirements and protect Medicaid expenditures?

6. **How has the misclassification of EpiPen® impacted the 340B program?** Because the 340B ceiling price is linked to the Medicaid rebate amount, how drugs are classified under the Medicaid Drug Rebate program would presumably affect the prices covered entities pay for drugs through the 340B program. Accordingly, what are the implications for covered entities in the 340B program from CMS allowing Mylan to misclassify EpiPen?
7. **Why did CMS apparently fail to act on EpiPen's® misclassification concerns sooner?** Numerous questions have been raised about the financial impact to the Medicaid program resulting from the misclassification of the EpiPen® product. Given the significant Medicaid expenditures at risk from misclassification, it is truly puzzling that CMS staff appear to have known about the misclassification of EpiPen for a year or two – but apparently failed to take any definitive remedial action to protect Medicaid expenditures. The delay raises questions about CMS's process for reviewing the case of Mylan's EpiPen® classification in particular. Who, in particular, was responsible for reviewing the question of Mylan's EpiPen® classification? Were staff concerns raised but ignored? Why did CMS decline to take sufficient remedial action over a period of more than a year? Did CMS staff charged with overseeing the Medicaid Drug Rebate Program disagree about the correct policy outcome in this particular case?

Thank you for your prompt attention to this serious matter. Given the significant financial impact to the Medicaid program and the strong bipartisan interest from Congress in understanding the facts of the situation in this case, we respectfully request the OIG begin its review as soon as practical. A targeted and timely review will help inform Congress, improve CMS's oversight of the Medicaid Drug Rebate Program, and increase the confidence of Medicaid stakeholders that the issues in this case are being appropriately reviewed by a respected, independent third party.

Sincerely,



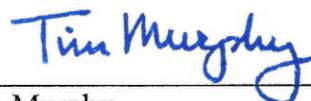
Fred Upton
Chairman
Committee on Energy and Commerce



Joseph R. Pitts
Chairman
Subcommittee on Health



Marsha Blackburn
Vice Chairman
Committee on Energy and Commerce



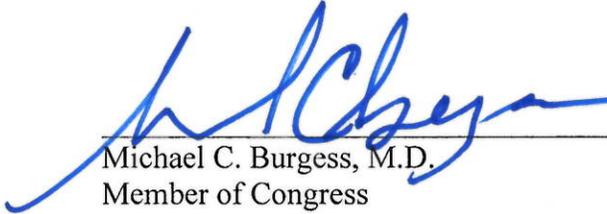
Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations



Brett Guthrie
Vice Chairman
Subcommittee on Health



Joe Barton
Member of Congress



Michael C. Burgess, M.D.
Member of Congress



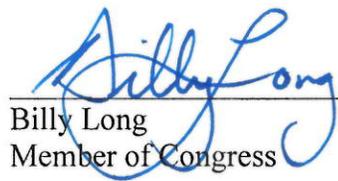
Leonard Lance
Member of Congress



H. Morgan Griffith
Member of Congress



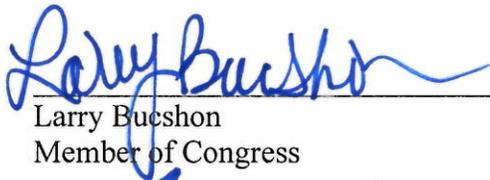
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