

Congress of the United States
House of Representatives
Washington, DC 20515-1308

October 7, 2016

Director Felicia F. Norwood
Illinois Department of Healthcare and Family Services
201 S Grand Avenue E.
Springfield, IL 62704

Dear Director Norwood:

I am writing to request that the Illinois Department of Healthcare and Family Services review payments made to Mylan Pharmaceutical (Mylan) for the EpiPen Auto-injector.

Recently, the U.S. Department of Health and Human Services' (HHS) Centers for Medicare and Medicaid Services (CMS) reported that Medicaid spending on Mylan Pharmaceutical's EpiPen product increased from \$66 million in 2011 to \$360 million in 2015. In total, Medicaid spending on EpiPens from 2011 to 2015 amounted to nearly \$1 billion.

Even accounting for rebates, net Medicaid spending on EpiPens from 2011 to 2015 was approximately \$794 million. However, it appears that even when providing a rebate, Mylan did everything in its power to protect its profit margins.

As CMS reported to Congress, "Under the Medicaid statute, regulation, guidance, and the rebate agreement that participating manufacturers sign, it is the manufacturer's responsibility to report accurate product and pricing data to the Medicaid Drug Rebate Program and pay proper rebate amounts." Yet despite CMS warning Mylan that its EpiPen product was incorrectly classified, Mylan persisted in classifying EpiPen as a generic drug under the Medicaid Drug Rebate Program, which enabled the company to avoid paying the higher rebate rate for brand-name drugs.

It is not abundantly clear why EpiPen's classification was incorrectly changed from a brand-name drug to a generic drug in 1997 under the Medicaid Rebate Program. It is also not clear why Mylan never acted to fix this problem after acquiring the EpiPen. However, it is clear that EpiPen is not a generic drug. EpiPen was approved under a New Drug Application by the U.S. Food and Drug Administration, providing Mylan patent protection, and there is no FDA-approved equivalent product.

The incorrect classification of the EpiPen as a brand-name drug for nearly two decades inflicted real harm on my constituents and the State of Illinois. Every additional dollar Illinois' Medicaid program was forced to pay because Mylan failed to provide the correct rebate amount, represents a dollar diverted away from helping our state's most vulnerable individuals obtain vital healthcare services.

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Accordingly, I am requesting that your Department share with my Office the total amount spent through Illinois' Medicaid program on EpiPens dating back to 2007. In addition, please provide the total rebate amount paid to Illinois' Medicaid program for EpiPens since 2007, and the difference between that incorrect rebate amount and the proper rebate amount Mylan would have paid if it accurately reclassified EpiPen as a brand drug.

Finally, please outline the specific actions the State of Illinois, in coordination with CMS, is taking to hold Mylan accountable and ensure Illinois taxpayers receive the appropriate rebate amounts for EpiPen expenditures. If Federal assistance is necessary, my office stands ready and willing to assist in your Department's efforts. Thank you in advance for consideration of my request.

Sincerely,



Tammy Duckworth
Member of Congress