DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

*Administrator*
Washington, DC 20201

OCT - 5 2016

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
United States Senate
Washington, DC 20510

Dear Senator Wyden:

Thank you for your letter to Secretary Burwell regarding the impact of Mylan Pharmaceutical's EpiPen pricing on Medicare and Medicaid. Beneficiary access to affordable prescription drugs is a priority at the Centers for Medicare & Medicaid Services (CMS). I share your concerns that unchecked price increases of pharmaceuticals that Americans depend on—such as the EpiPen—directly impact the health and financial status of our beneficiaries, our states, and the Federal budget.

Medicare and Medicaid spending on EpiPen has increased from $86 million in 2011 to $487 million in 2015, or 463 percent, not accounting for Medicaid or Medicare rebates or other post point-of-sale concessions.[1] These payments are summarized in the tables below and enclosed.

**Table A: Medicaid and Medicare Part D Expenditures on EpiPen, EpiPen 2-Pak, and EpiPen Jr 2-Pak, 2011-2015**

*Note: Medicaid expenditures include both federal and state expenditures. These amounts do not reflect manufacturer rebates for Medicaid or Medicare Part D.*

| Year | Total Medicaid | Total Medicare Part D | Total Medicaid and Medicare Part D |
|---|---|---|---|
| 2011 | $66,379,105 | $20,077,782 | $86,456,887 |
| 2012 | $117,895,582 | $41,743,251 | $159,638,833 |
| 2013 | $157,551,178 | $62,998,848 | $220,550,026 |
| 2014 | $253,208,380 | $88,110,768 | $341,319,148 |
| 2015 | $365,042,331 | $121,709,036 | $486,751,367 |
| Total 2011-2015 | $960,076,576 | $334,639,684 | $1,294,716,260 |

From 2011 through 2015, total Medicaid spending on EpiPen was $960 million, increasing from $66 million in 2011 to $365 million in 2015.[2] After rebates, net Medicaid spending over this five-year period was approximately $797 million, reflecting a rebate of 13 percent. Medicaid and Children's Health Insurance Program (CHIP) payment rates to pharmacies are set by the states.

[1] Throughout this letter, Medicaid spending refers to both federal and state expenditures.
[2] Total Medicaid spending includes EpiPen spending for the Children's Health Insurance Program (CHIP) in state CHIP programs that are not administered separately from the Medicaid program.

From 2011 through 2015, total Medicare spending on EpiPen was $335 million, increasing from $20 million in 2011 to over $121 million in 2015. These costs do not reflect manufacturer rebates or other post point-of-sale price concessions. Under Medicare Part D, Medicare pays a partially capitated amount to health plans to provide the prescription drug benefit to Medicare beneficiaries. As such, Medicare does not directly pay for any particular prescription, and the plans' payments for particular drugs are based on their negotiations with pharmacies and manufacturers. Additionally, enclosed with this letter is information regarding your requests related to reimbursements for Adrenaclick and Auvi-Q.

There are questions about the classification of EpiPen under the Medicaid Drug Rebate Program, which has a direct bearing on the net affordability to states. A review of our records indicates that, prior to 1997, EpiPen was reported as a single source, or brand drug, for the Medicaid Drug Rebate Program. Since the fourth quarter of 1997, EpiPen has been reported as a non-innovator multiple source, or generic drug. EpiPen is approved under a New Drug Application (NDA) by the Food and Drug Administration (FDA), has patent protection, and has no FDA-approved therapeutic equivalents. These facts indicate EpiPen does not meet the definition of a multiple source drug, but, in fact, meets the definition of a single source drug or brand drug. 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. This incorrect classification has financial consequences for the amount that federal and state governments spend because it reduces the amount of quarterly rebates Mylan owes for EpiPen. As you indicated in your letter, under the Medicaid Drug Rebate Program, single source or brand drugs pay a rebate of the greater of 23.1 percent of average manufacturer price (AMP) or the difference between AMP and the drug's best price, increased by an additional rebate if the AMP of the drug increased faster than the rate of inflation. In contrast, the rebate for generic products is 13 percent of AMP.[3] At this time, CMS cannot comment on the total amount of rebates owed by Mylan related to this incorrect classification.

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. When it comes to CMS's attention that the manufacturer's categorization is incorrect, CMS notifies the manufacturer and tries to reach an agreement. Manufacturers that fail to accurately report product and pricing data to the rebate program and pay insufficient rebates may be subject to liability under the False Claims Act, a penalty of up to $100,000 per item of false information under the Rebate Agreement, or other government actions or claims. Additionally, the Covered Outpatient Drug final rule[4] published in February 2016 provides enhanced safeguards to ensure the proper classification of drugs.

CMS believes it is critically important to ensure that manufacturers accurately classify their drugs in the Medicaid Drug Rebate Program and has taken several steps to achieve this goal.

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[3] The Bipartisan Budget Act of 2015 added an additional inflation-based rebate for generic drugs in the Medicaid Drug Rebate program that takes effect January 1, 2017.

[4] The Covered Outpatient Drug final rule can be found at https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf.

The Covered Outpatient Drug final rule reiterated our previous guidance that covered outpatient drugs that are approved by the FDA under an NDA should be reported to CMS as a single source or innovator multiple source drug. Moreover, the final rule provided that such drugs are to be reported as a single source or innovator multiple source drug by default, unless the manufacturer applies for, and CMS grants in writing, an exception to classify the drug as a non-innovator multiple source drug. This is a narrow exception, which is available in very limited circumstances. The final rule and guidance issued after the rule's publication make clear that covered outpatient drugs that have patent protection or statutory exclusivity will not qualify for the exception. Manufacturers of drugs currently reported as non-innovator multiple source drugs but marketed under an NDA have four quarters from the rule's April 1, 2016, effective date (until March 31, 2017) to submit an exception request before CMS will take administrative action against the manufacturer. CMS's decision to allow manufacturers up to four quarters to come into compliance before taking administrative action in no way relieves manufacturers of other potential liability. Regarding new drugs that enter the Medicaid Drug Rebate Program and are marketed under an NDA, manufacturers must report them as either single source or innovator multiple source drugs, unless or until those manufacturers apply for the narrow exception and CMS confirms in writing that the exception applies. These safeguards will help ensure that manufacturers are properly and consistently classifying drugs in the future.

We take the issue of drug misclassification seriously. To this end, we work with manufacturers in instances where they have appeared to have misclassified their drugs in the Medicaid Drug Rebate Program to achieve the appropriate classification. We have undertaken a comprehensive review of our database to identify such instances. It is possible that certain drugs may qualify for the narrow exception described above. Until we review all of the exception requests and supporting documentation, however, we will not be able to say definitively how many drugs may qualify for the narrow exception.

Thank you again for taking the time to write about this important matter. I look forward to continuing to work with you and your colleagues to maintain strong Federal health programs so that the nation's Medicare and Medicaid beneficiaries can continue to access the services to which they are entitled. If you have any additional questions, please contact the CMS Office of Legislation at 202-690-8220. I will also provide this response to Representative Pallone.

Sincerely,

Andrew M. Slavitt
Acting Administrator

Enclosure

**Enclosure A**

## Medicaid

Each state determines its own provider reimbursement levels for covered outpatient drugs. While states must comply with Federal laws and regulations concerning provider reimbursement, actual rates paid vary by state.

States determine whether to implement cost-sharing for covered outpatient drugs. Under statute and regulation, out-of-pocket costs for drugs are limited to nominal amounts for most individuals. For FY2011-2013, the maximum cost-sharing states may implement for drugs was $3.65, $3.80, and $3.90, respectively. For 2013-2015, beginning January 1, 2014 the maximum cost-sharing states may implement for drugs is $4 for preferred drugs and $8 for non-preferred drugs. For FY2016, these amounts were adjusted for inflation to $4.10 and $8.20 for preferred/non-preferred drugs. For beneficiaries with income above 150% of the federal poverty level, maximum cost-sharing was $4 for preferred drugs and they may be charged higher cost sharing for non-preferred drugs up to a maximum of 20% of the state agency's cost for such non-preferred drugs.

**Table A: Medicaid Expenditures on EpiPen, Adrenaclick and Auvi-Q, 2011-2015**

*Note: These amounts do not reflect manufacturer rebates.*

| Year | Total Amount EpiPen | Total Amount Adrenaclick | Total Amount Auvi-Q |
|---|---|---|---|
| 2011 | $66,379,105 | $13,776 | $0 |
| 2012 | $117,895,582 | $182 | $0 |
| 2013 | $157,551,178 | $2,804 | $ 3,753,672 |
| 2014 | $253,208,380 | $5,019 | $ 9,070,229 |
| 2015 | $365,042,331 | $3,465 | $14,287,185 |

## Medicare

**Table B: Total Medicare Part D Expenditures on EpiPen, Adrenaclick and Auvi-Q, 2011-2015**

*Note: These amounts reflect the total amount paid at the Point of Sale, and do not reflect any subsequent rebates paid by the manufacturer.*

| Year | Total Amount EpiPen | Total Amount Adrenaclick | Total Amount Auvi-Q |
|---|---|---|---|
| 2011 | $20,077,782 | $5,942 | $0 |
| 2012 | $41,743,251 | $447 | $0 |
| 2013 | $62,998,848 | $250 | $989,420 |
| 2014 | $88,110,768 | $3,123 | $3,439,889 |
| 2015 | $121,709,036 | $621 | $4,190,563 |

**Table C: Average Medicare Part D Gross Drug Cost per Prescription Drug Episode for EpiPen 2-Pak, Adrenaclick and Auvi-Q, 2011-2015**

*Note: These amounts reflect the total amount paid at the Point of Sale, and do not reflect any subsequent rebates paid by the manufacturer.*

| Year | Average Amount EpiPen 2-Pak | Average Amount Adrenaclick | Average Amount Auvi-Q |
|---|---|---|---|
| 2011 | $170 | $152 | N/A |
| 2012 | $217 | * | N/A |
| 2013 | $267 | * | $274 |
| 2014 | $357 | * | $400 |
| 2015 | $466 | * | $487 |

N/A - No applicable claims.

* – Fewer than ten applicable claims. CMS policy is typically not to reveal information impacting ten or fewer beneficiaries.

**Table D: Average Medicare Beneficiary Payment at Point of Sale for EpiPen 2-Pak, Adrenaclick and Auvi-Q, 2011-2015**

*Notes:*

- *Figures do not include beneficiaries enrolled in the Low Income Subsidy (LIS). The LIS pays for cost-sharing at Point of Sale.*
- *Figures do not reflect payments made by other third party payers that assist beneficiaries with cost sharing or pharmaceutical manufacturer coverage gap discounts.*
- *Some Part D plans include enhanced cost sharing support as a benefit. These figures do not reflect the additional cost sharing support paid by plans.*

| Year | Average Beneficiary Payment EpiPen 2-Pak | Average Beneficiary Payment Adrenaclick | Average Beneficiary Payment Auvi-Q |
|---|---|---|---|
| 2011 | $48 | $52 | N/A |
| 2012 | $55 | * | N/A |
| 2013 | $54 | * | $68 |
| 2014 | $59 | * | $73 |
| 2015 | $69 | * | $74 |

**Additional Note:**

CMS recently released a Public Use File with Part D prescribing information for 2014. This PUF follows the release of a similar file last year for 2013. PDE data for prior years changes continuously as CMS works with Part D plans to create a more accurate record of past transactions. As such, the figures provided above will not necessarily be consistent with those PUFs because the data pull date is more recent.