

The Right Rebate Act of 2019

In 2016, a whistleblower lawsuit filed under the False Claims Act against Mylan resulted in a \$465 million settlement with the U.S. Justice Department. The lawsuit resolved claims that the pharmaceutical company misclassified the EpiPen as a generic drug as a part of the Medicaid Drug Rebate Program (MDRP). That misclassification resulted in Mylan paying lower rebates to the program.

The settlement may reflect only a fraction of the amount Mylan underpaid. An analysis by the U.S. Department of Health and Human Services Office of Inspector General (OIG) found that taxpayers may have overpaid for EpiPen by as much as \$1.27 billion over a 10 year period.

The discrepancy between the settlement the company paid back to taxpayers and the OIG estimate is extremely concerning. Moreover, the Centers for Medicare & Medicaid services (CMS) was made aware of the misclassification for years but did nothing.¹ In addition, another OIG report found that other drugs were misclassified in the same manner.² Currently, HHS and the HHS OIG do not have the explicit authority to force companies to reclassify their drugs and impose civil monetary penalties for a misclassification.³ Thus, there exists a major gap in the statutory scheme for the MDRP. The potential price tag for not fixing this loophole could be in the billions of dollars.⁴

The Right Rebate Act of 2019:

- Closes the loophole that Mylan, and others, exploited by providing authority to the Secretary of HHS to reclassify drugs, impose civil monetary penalties, and recover incorrect rebate payments.
- Creates oversight mechanisms such as a requirement that HHS provide reports to Congress about how its new authorities have been used and the actions taken to reclassify drugs. Overall, the legislation will prevent the EpiPen fiasco from happening again.

High prescription drug prices are a major concern across the country. As part of bringing down drug costs, it is necessary to ensure that companies that take part in federal health care programs aren't gaming the system. Companies should be treating consumers *and* taxpayers fairly.

¹ <https://www.grassley.senate.gov/news/news-releases/grassley-latest-estimate-taxpayers-overpaid-127-billion-epipen>

² <https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf>

³ <https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf>, p 14.

⁴ <https://www.grassley.senate.gov/news/news-releases/grassley-latest-estimate-taxpayers-overpaid-127-billion-epipen>; <https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf>