Federal government: Mylan has been overcharging for EpiPens

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In this Wednesday, Sept. 21, 2016, file photo, Mylan CEO Heather Bresch holds up EpiPens while testifying on Capitol Hill in Washington, before the House Oversight Committee hearing on EpiPen price increases. Now the federal government, responding to Congressional inquiries, says EpiPen's maker has been overcharging Medicaid for years because the emergency shot is classified incorrectly as a generic medicine, so Mylan has been paying the government much-lower rebates off the price than it should. (AP Photo/Pablo Martinez Monsivais, File)

Even the federal government is apparently paying too much for EpiPens, along with angry patients and insurers.

The skyrocketing price of the life-saving allergy shot, which has triggered a storm of criticism, is only part of the problem. Now the federal government, responding to Congressional inquiries, says Medicaid for years has been paying too much for EpiPens because the emergency shot is classified incorrectly as a generic medicine.

The federal government says EpiPen is a branded drug, which means the drug's maker, Mylan, should have been paying the government a far higher rebate under the government's complex pricing rules.

Mylan, which has been blasted for hiking the price of a pair of EpiPens to $608 from $94 since 2007, denies wrongdoing. It says that EpiPen meets Medicaid's definition of a generic product and that it was classified that way when Mylan acquired rights to the product in 2007.

The company could face steep penalties, though.

According to the Centers for Medicare & Medicaid, manufacturers that pay insufficient rebates may be fined by the Department of Health and Human Services for violating the rebate rules, sued for overcharging the government or hit with other penalties.

CMS spokesman Aaron Albright would not comment Thursday on whether the agency would try to correct the misclassification of EpiPen, recoup money, or seek penalties from Mylan.

But in a letter sent late Wednesday to senators and congressmen probing EpiPen's exorbitant price hikes, Andy Slavitt, acting director of CMS, wrote that EpiPen doesn't meet the definition of a generic drug because it was approved as a brand-name drug and is protected by a patent.

Slavitt wrote that CMS "has expressly told Mylan that the product is incorrectly classified."

Albright couldn't immediately say when Mylan was told that, but said the pharmaceutical industry was given guidelines explaining the classifications in 2010.

For nine years, the government says, Mylan has been paying rebates of 13 percent, as required for generic products when it should have been paying the 23.1 percent rebate required for brand-name drugs.

In addition, CMS said Mylan hasn't been paying Medicaid a second rebate that is required whenever the price of a brand-name drug price rises more than inflation. The price of an Epipen pack rose 23 percent a year on average between 2007 and 2016. Inflation has averaged less than 2 percent a year over the same period.

The prior maker of EpiPen apparently also was underpaying. CMS records indicate the product's status was changed from brand-name to generic in the fourth quarter of 1997, according to Slavitt's letter. It's unclear why the change was made.

Mylan said in a statement that it "simply continued to classify the product the same way," as that was "consistent with longstanding written guidance from the federal government."

The amount Medicare and Medicaid spent on EpiPens rose to $486.8 million in 2015 from $86.5 million in 2011, a jump of 463 percent, Slavitt's letter says.

In response, Senate Finance Committee member Ron Wyden, D-Oregon, and House Energy and Commerce Committee member Frank Pallone, D-New Jersey, said in a statement that Mylan is "bilking taxpayers out of

millions of dollars."

Mylan shares fell 3 percent to $36.84 Thursday.