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Grassley Continues To Press CMS on Medicaid Drug Rebate Classifications: What Will Be the Fallout?

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Back in early October, we were all transfixed by the announced Mylan settlement with the U.S. Department of Justice (DOJ) over Mylan's alleged underpayments of Medicaid Drug Rebates for the EpiPen. Although Mylan indicated that its $465 million settlement resolved all potential liability to government programs over EpiPen's classification for Medicaid Drug Rebate purposes, DOJ would not confirm the specifics of the settlement and it appeared that no actual settlement documents had even been drafted. We **blogged** our thoughts that the "settlement" was actually a handshake deal that had not been reduced to writing, had not been agreed to by the states, and had left the extent of any releases and future compliance to be negotiated. And we said Congressional scrutiny would not end due to the announced settlement.

Multiple state and government officials **decried** the announced settlement as inadequate. Senator Grassley went so far as to schedule a Senate hearing on the settlement, but was forced to **postpone** it when no one from DOJ or Mylan would agree to attend and testify.

Then the election intervened, and EpiPen rebates were yesterday's news. However, Senator Grassley, for one, is not letting go. But at this point, his focus is more on government action, or inaction, over drug classifications. And depending on what his inquiry reveals, it may end up hurting, not helping, any government case against Mylan, and potentially other drug manufacturers, based on classification of drugs for purposes of Medicaid Drug Rebates.

How Did We Get Here?

When it comes to the Medicaid Drug Rebate program, manufacturers pay lower rebate percentages on generic drugs than they do on brand-name or innovator drugs. Brand or innovator drugs are also assessed a rebate "inflation penalty" when price increases outpace inflation; generic drugs are not subject to the inflation penalty. So whether a drug is classified as a brand/innovator drug or a generic drug, impacts the bottom line of the rebates that drug manufacturers must pay state Medicaid programs.

Moreover, while the states are the beneficiaries of the Medicaid rebates, it is CMS that controls manufacturer price reporting requirements for rebate purposes. And it was CMS who told the EpiPen manufacturer in 1997 that while the "pen" was an innovator product, the "epi" part (epinephrine) was a generic drug; therefore for Medicaid Drug Rebates purposes, the manufacturer could classify and report the EpiPen as a generic drug. The result of CMS' action was that the EpiPen was subject to lower rebates and not subject to the inflation penalty when its price increased.

In July 2009, OIG released its review on the ***Accuracy of Drug Categorizations for Medicaid Rebates***. According to OIG, there were eight drugs CMS classified as generic for purposes of Medicaid Drug Rebates but classified as innovator drugs (and received the benefits of that classification) for FDA purposes. OIG said that if those eight drugs had also been classified as innovator brand by CMS, the resulting Medicaid rebate payments would have increased by nearly $14 million/quarter. The OIG report did not name the drugs at issue.

Then in the fall of 2016, media focus on significant price increases for the EpiPen hit on the fact that Mylan had continued to pay generic-level rebates on the EpiPen. It was argued that if the EpiPen had been treated as a brand/innovator drug for Medicaid Rebate purposes, it would have paid higher rebates and the inflation penalty would have been triggered, which would have resulted in hundreds of millions in extra Medicaid Drug Rebate payments for the states.

Where Are We Now?

There was a missing link in the arguments against Mylan. What did CMS do in the face of the 2009 OIG report? CMS **said** that sometime after the 2009 OIG report, it provided "additional guidance" to manufacturers on drug classification, including discussions with Mylan about the EpiPen – but specifics have not been forthcoming. If CMS never affirmatively withdrew its 1997 letter and replaced it with something in writing, why shouldn't a manufacturer assume that the letter represents CMS' ongoing position?

And while our attention may have been diverted on other matters, Senator Grassley has remained focused.

- OIG generally provides a draft copy of reviews to an agency before a report is finalized. Grassley's staff has confirmed that in March 2009, before the OIG report was finalized and published, CMS requested and received the specifics on the drugs that OIG asserted were misclassified for rebate purposes. Those drugs did include the EpiPen, as well as two other widely used products, Dilaudid and Prilosec.
- On December 6, 2016, Grassley secured OIG's commitment to do an updated review of CMS' classification of drugs for Medicaid Drug rebate purposes.
- On January 4, 2017, Senator Grassley demanded from CMS a specific response, because "*Congress and the American public have a right to know what additional steps, if any, CMS took to hold Mylan and other companies accountable"* after it received the names of the misclassified drugs from OIG in 2009.

Given how much pressure the drug industry has been under, it was easy to jump to conclusions that the government was defrauded of Medicaid Drug Rebates due to the Epi-Pens' classification as generic. But can you be defrauded of what you actually know? Grassley's continuing investigation is building the case that CMS may be at fault for failing to timely act on misclassification of the EpiPen and other drugs, after it was clearly notified of the issue in 2009.

So while we will be looking forward to CMS' response to Senator Grassley, you can bet the manufacturers of the EpiPen, Dilaudid and Prilosec are even more eager to see what CMS actually produces. According to the Supreme Court's 2016 ruling in ***United Health Services v. United States ex rel. Escobar,*** to be an actionable false claim, a company's misrepresentation, such as the classification of a drug for rebate purposes, must be **material** to the government – it must matter to the government. If CMS failed to jump on these drug classifications in 2009, will the government really be able to pursue manufacturers and argue with a straight face that the classifications for purposes of Medicaid Drug Rebate were material and mattered?

Authors