## Rewards for Reporting Medicaid "Best Price" Violations under the Medicaid Rebate Statute: Why aggregating or stacking drug manufacturer rebates paid to unrelated entities must be included in *Best Price* calculation

This article outlines how to receive a whistleblower reward for reporting Medicaid *best price* fraud when a drug manufacturer fails to aggregate or stack rebates paid to unrelated entities in calculation of best price under the Medicaid Rebate Statute and Rebate Agreement.

It is typical for a drug company to pay rebates to two unrelated entities in the process of selling a single pill to a single patient. However, some drug companies do not include both rebates in the calculation of best price. It is my law firm's position that this is wrong. Under the False Claims Act, a whistleblower is entitled to a reward of up to 30% of the amount of rebates the drug company must pay Medicaid based upon you blowing the whistle for under-reporting true best price. Because drug companies sell millions of pills to Medicaid patients, the amount of the whistleblower reward may be in the tens-of-millions of dollars.

In the 1990's, Congress enacted the Medicaid Rebate Statute requiring drug manufacturers to charge Medicaid its lowest price or "best price" as it charges to any favorite customers. Each quarter, a drug company must report its best price and give Medicaid a rebate accordingly. The Rebate Statute defines best price as: The lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity. It also specifies that best price shall be inclusive of all discounts and rebates. 42 U.S.C. 1396r-8(c)(1)(C). Some drug companies might try to argue that the word "any" is vague and could possibly mean that it must only report just one of two rebates paid because any might mean a rebate to just one entity and not all rebates. However, drug companies all sign a Rebate Agreement that clarifies that a manufacturer's best price is "the lowest price at which the manufacturer sells the drug to any purchaser in the United States in any pricing structure," and the price is "adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized." 56 Fed. Reg. 7049. In short, a drug manufacturer must calculate its best price based upon the amount it realizes from the sale of a single pill to a single patient. It does not mean the highest rebate to one of two entities when both rebates are needed to make the sale of a single pill to a single patient.

Here is an example. Jane Doe is a patient at a long term care facility and has health insurance. Because there are several drugs that could treat her condition, Jane has choices of which drug manufacturer to use. Because of competition, health insurance companies, hospitals and pharmacies often ask for rebates or discounts. Assume that a drug manufacturer must pay a rebate of 23.1% to the health insurance company to get a drug on its formulary. If it does not pay the rebate, the health insurance company won't pay for the drug and Jane will use a different drug from a competing drug company. Also assume that the pharmacy at the long term care facility also demands a rebate of 9% to stock the drug on its shelf. If the drug company does not pay the rebate, Jane likely will ask her doctor to prescribe a drug that is in the pharmacy so she does not have to ask a relative to go pick it up at another location. Thus, Jane will only buy the drug if it is both on her drug company's list of approved drugs and stocked in her chosen pharmacy.

The question is whether the drug company must stack or aggregate both sets of rebates (the 23.1% paid to the health insurance company and the 9% paid to the pharmacy) when calculating its best price. There is no dispute that both of the rebates affect the drug company's price realized. Only if the drug company paid both rebates would a sale even occur. Because the Rebate Agreement requires a drug company to account for any pricing structure and include cumulative discounts and all arrangements that adjust the price the drug company realizes, both sets of rebates must be aggregated or stacked even though they are paid to two different entities. Therefore, the best price the drug manufacturer must report is a discount of 32.1%. If the drug company only reported the discount of 23.1%, it owes Medicaid an additional rebate of 9% for all of the drugs sold to Medicaid patients, which could be millions of dollars.

In 2005, when the Centers for Medicare & Medicaid Services (CMS) was amending regulations pertaining to *best price*, it stated in its preamble that best price means any discounts or rebates that affect a drug manufacturers price realized. In 2007, a few drug companies wrote letters complaining about how CMS was interpreting best price. They asked CMS to change the definition of best price. CMS not only did not change the regulations but reiterated a dozen times that best price means the price the manufacturer realizes. Thus, if a drug company fails to aggregate or stack rebates or discounts to two unrelated entities, it may be cheating Medicaid by under-reporting the true lowest or best price charged to favored customers.

In 2016, when CMS was again modifying some regulations pertaining to best price, a similar question was asked about whether a drug manufacturer must stack together or aggregate rebates paid to two unrelated entities. CMS answered this same tired question in the affirmative. CMS stated: "A manufacturer is responsible for including all price concessions that *adjust the price realized by the manufacturer* for the drug in its determination of best price," including when price concessions are given to "two entities." 81 Fed. Reg. 5170, 5252-53 (Feb. 1, 2016).

In sum, both the Rebate Agreement and CMS guidance unambiguously requires a drug manufacturer to base best price on the amount it "actually realized" and must take into account "cumulative discounts, rebates or other arrangement." This includes when discounts or rebates are given to "two entities." 81 Fed. Reg. 5170, 5252-53. Accordingly, a drug manufacturer must aggregate or stack rebates paid to unrelated entities in the process of selling a single pill to a single patient when calculating best price.

If you have inside information that a pharmaceutical company is not aggregating or stacking rebates to two unrelated entities when calculating best price, you may be entitle to a significant whistleblower reward for reporting fraud against Medicaid. Contact Mr. Hesch to have his law firm assess your allegations that a drug manufacturer was defrauding Medicaid under the Medicaid Rebate Statute by underpaying *best price* rebates.

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Exclusively representing whistleblowers file for rewards for reporting fraud against the government.

See the link at the bottom of the Hesch Firm website (<u>www.HowToReportFraud.com</u>) "Do I have a case" to have Mr. Hesch review your potential whistleblower reward case of a pharmaceutical or drug company cheating Medicaid under the Medicaid Rebate Statute because it did not stack or aggregate rebates paid to two unrelated entities. You could be eligible for a significant reward.