

Federal Drug Discount and Compliance Monitor



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...**BREAKING NEWS**...

HHS IG Explains Withdrawal of 340B Report

The US Department of Health and Human Services Office of Inspector General (OIG) has provided more details on its recent decision to withdraw its June 2004 report on the accuracy of 340B pricing, citing “problems with the underlying data used in developing the report’s findings.”

In a November 4 memorandum addressed to Centers for Medicare and Medicaid Services (CMS) Administrator Mark McClellan and Health Resources and Services Administration (HRSA) Administrator Elizabeth Duke, Acting Inspector General Daniel Levinson explained that “CMS had inadvertently provided us with ceiling price data from the wrong time period,” and that the OIG failed to correctly determine the package size for some sampled drugs.

According to the letter, the report underrepresented the package sizes for some drugs that are measured in liquid volume or weight as opposed to pills or capsules, such as products sold in vials, inhalers, or ointments. As a result, the government may have consistently underestimated the ceiling price for at least some of these products.

Levinson says that the inaccuracies in the report were discovered when OIG began its effort to conduct a follow-up study on 340B overcharges. The purpose of the new study, which was announced in the HHS/OIG Work Plan for FY 2005, will be to determine the causes of the price discrepancies outlined in the June report.

Despite the errors in the data, “we continue to believe that there are systemic issues that lead to price discrepancies within the 340B Drug Pricing Program,” Acting Inspector General Levinson wrote.

Levinson added that “the newly-discovered data problems do not affect the validity of three findings in the report,” including weaknesses in HRSA’s oversight of the program, the inability of covered entities to independently verify 340B prices, and the fact that manufacturers’ 340B data are not verified against HHS calculations.

Nonetheless, the OIG does not plan to re-release the June study until they have conducted a more comprehensive review.

“For the immediate future, rather than reissuing the report at this time, we are planning a more systematic review of the accuracy and completeness of the data used to calculate 340B ceiling prices,” the letter states.

More details about the withdrawal of the report and the next steps OIG plans to take on the 340B program will be included in the next issue of the Monitor which will be published next week.

A copy of Acting Inspector General Levinson’s memorandum can be found at <http://www.oig.hhs.gov/oei/reports/oei-05-02-00070.pdf>.