



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

NOV 4 2004

Washington, D.C. 20201

TO: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Elizabeth M. Duke, Ph.D.
Administrator
Health Resources and Services Administration

FROM: Daniel R. Levinson *Daniel R. Levinson*
Acting Inspector General

SUBJECT: *Appropriateness of 340B Drug Prices (OEI-05-02-00070)*

In June 2004, the Office of Inspector General (OIG) issued a report entitled *Appropriateness of 340B Drug Prices (OEI-05-02-00070)* (the Report), which evaluated whether participants in the Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program receive the discounted prices required by the Public Health Service Act (PHS Act). On October 21, 2004, the OIG withdrew the Report because problems with the underlying data used in developing our findings were discovered.

The PHS Act requires pharmaceutical manufacturers to sell covered outpatient drugs at or below a statutorily-defined price, known as the 340B ceiling price, to qualified entities, e.g., public hospitals, community health centers, etc. If a manufacturer fails to sell covered outpatient drugs at or below the ceiling price, it can be terminated from the Medicaid drug rebate program and its products will not be eligible for Medicaid reimbursement.

On behalf of HRSA, the Centers for Medicare & Medicaid Services (CMS) calculates the Government's record of the 340B ceiling price. To evaluate whether qualified entities receive the 340B ceiling price, we compared CMS's calculation of the ceiling price to the invoice prices paid by 37 sampled 340B providers. We found that 31 percent of the invoice prices exceeded the 340B ceiling price, resulting in an estimated \$41 million difference for the month of September 2002. We did not attempt to assess the cause for the estimated difference between CMS's calculated ceiling price and the price paid by the entities, as that was not the objective of our study.

After the Report's initial release, a variety of stakeholders, including HRSA, several Congressional committees, pharmaceutical manufacturers, and 340B advocacy groups, expressed support for additional analysis of our findings to understand the possible reasons for these overpayments. As a result, we initiated a follow-up study intended to establish and explore the potential causes for the price differences. During the course of this follow-up work, we discovered two issues that led to our withdrawal of the Report. First, we discovered that CMS had inadvertently provided us with ceiling price data for the wrong time period. We have since obtained information for the correct time period.

Second, based on conversations with knowledgeable industry representatives, we learned of a potential weakness in CMS's application of package size information in the ceiling price calculation.

Pursuant to the PHS Act, the 340B ceiling price is based on pricing information that pharmaceutical manufacturers supply to CMS to calculate the unit rebate amount for the Medicaid drug rebate program. The Medicaid unit rebate amount is based on the per-unit cost of a drug, *e.g.*, one tablet, whereas the 340B ceiling price represents package prices, *e.g.*, a bottle of 100 tablets. Therefore, to calculate the 340B ceiling price, CMS must multiply the product's per-unit cost by the total package size.

For prescription drugs measured by liquid volume or weight, such as products sold in vials, inhalers, or as ointments, the notation for the package size is more complex than for drugs dispensed in discrete units, like pills or capsules. The package size for drugs with volume or weight measurements are expressed with an "amount x unit" notation. For example, the Food and Drug Administration (based on information provided when manufacturers register their products) lists the package size for one particular liquid prescription drug as "5 X 3ML." This represents a package of 5 vials, each containing 3 milliliters per vial. To calculate the package size, it is necessary to multiply the number of milliliters, 3, by the number of vials, 5, for a total package size of 15. However, the package size CMS uses in its calculation of the 340B ceiling price is listed as 3.

CMS obtains package size data for its 340B ceiling price calculation from First Databank, a contracted provider of prescription drug information. While most of CMS's package size data appear to be complete, we found that using First Databank's package size for drugs sold by volume or weight does not capture the full computation necessary to reflect a product's actual package size. This results in a consistently underestimated ceiling price for certain products. Based on the example above, CMS would calculate a 340B ceiling price that would underestimate the actual 340B ceiling price by a factor of five.

Despite our withdrawal of the Report because of problems with the underlying data, we continue to believe that there are systemic issues that lead to price discrepancies within the 340B Drug Pricing Program. These newly-discovered data problems do not affect the validity of three findings of the Report. First, we found weaknesses in HRSA's oversight of the Program in that it has no process in place to confirm that 340B entities receive the ceiling price. Second, we found that participating entities cannot independently verify that they receive the 340B ceiling price due to confidentiality provisions in the authorizing statute. Finally, we found that pharmaceutical manufacturers' 340B ceiling price calculations are not verified against the Department's calculations of the 340B ceiling price. In fact, pharmaceutical manufacturers are not required to and do not report their ceiling prices to the Department. We appreciate HRSA's positive response to these previous recommendations and anticipate it will continue to make progress in addressing these issues.

To describe accurately the extent to which the pricing discrepancies identified in our Report exist, and the underlying reasons for the variations, we need to conduct further 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, as well as of any discrepancies between amounts paid by 340B entities and the ceiling prices. We also plan to review the entire 340B Drug Pricing Program system to identify other potential causes for price discrepancies. We look forward to working with CMS and HRSA as we continue our reviews.