

# THE 340B COALITION

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October 16, 2003

Elizabeth Duke, Ph.D.  
Administrator  
Health Resources and Services Administration  
5600 Fishers Lane  
Room 14-05  
Rockville, Maryland 20857

VIA FACSIMILE

**Re: Inspector General Report on 340B Overcharges**

Dear Dr. Duke:

This letter follows up on our previous correspondence to you of April 21, 2003, a copy of which is attached. As we emphasized in that letter, the organization we represent – the 340B Coalition – strongly endorses HRSA's plan for recovering overcharges on drugs purchased under the federal 340B discount program, as outlined in Comments on the Inspector General's audit report of March 10, 2003, entitled *Pharmaceutical Manufacturers Overcharged 340B – Covered Entities* ("the Report").<sup>1</sup> We are concerned, however, that despite the passage of seven months since issuance of the report, we have received no information that HRSA has gone forward with the actions necessary to put its implementation plan into effect.

Specifically, HRSA's comments expressly stated a plan to notify the drug manufacturers who were the subject of the report, and request that they take a series of five corrective actions to achieve appropriate reimbursement of drug overcharges to affected 340B covered entities. Although we had understood that these notification letters had been prepared some time ago, we see no evidence that they have been sent to any of the involved pharmaceutical manufacturers. Indeed, our understanding is that HRSA has not yet formally submitted a "final management decision" and action plan to the Inspector General (IG) and other relevant HHS authorities, despite the IG's request that this decision and plan be finalized and transmitted within 60 days of issuance of the report. We urge HRSA to expedite the remediation process described in the March 10<sup>th</sup> report.

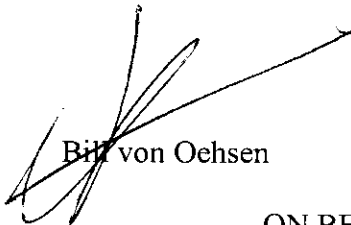
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<sup>1</sup> We refer here to the document entitled *Health Resources and Services Administration's Comments on the Office of Inspector General's Draft Report: "Pharmaceutical Manufacturers Overcharged 340B Covered Entities"* Code #A-06-01-00060, which was transmitted to the Inspector General on or about January 7, 2003, and included as an appendix to the March 10 OIG Report.

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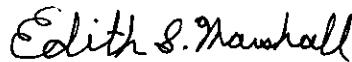
We are aware that HRSA has undergone an internal reorganization, and that it has many important tasks within its areas of responsibility. At the same time, particularly in the current economic climate, financial recoveries are of critical importance to 340B providers and programs that have been overcharged for drug therapies needed by their patients. We sincerely hope that appropriate action will be taken in the very near future to initiate HRSA's implementation process plans, and to assist 340B entities in recouping the payments to which they are entitled as a result of past overcharges from pharmaceutical manufacturers.

Please contact us if there is anything that the 340B Coalition or its members can do to assist in HRSA's efforts respecting the March 10 report, or more generally in efforts to improve the integrity of the 340B program. Any questions or other requests may be directed to Bill von Oehsen, Ted Slafsky, or Edith Marshall, all of whom can be reached on (202) 466-6550.



Bill von Oehsen

Sincerely,



Edith Marshall



Ted Slafsky

ON BEHALF OF THE 340B COALITION

cc: Dara Corrigan  
Dennis Williams  
Jim Mitchell  
Mary Riordan