

# THE 340B COALITION

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November 19, 2010

CDR Krista Pedley  
Director, Office of Pharmacy Affairs  
Health Systems Bureau  
Health Resources and Services Administration  
5600 Fishers Lane  
Parklawn Building, Room 10C-03  
Rockville, MD 20857

## **Re: Comments on 340B Manufacturer Civil Monetary Penalties**

Dear CDR Pedley:

On behalf of the thousands of providers enrolled in the 340B federal drug discount program, the 340B Coalition respectfully submits this letter in response to the September 20, 2010 Advance Notice of Proposed Rulemaking (ANPRM) and Request for Comments regarding application of civil monetary penalties (CMPs) to manufacturers participating in the 340B drug pricing program. With this comment, the Coalition seeks to ensure that the government's new CMP authority is exercised effectively and responsibly.

The 340B Coalition consists of eleven national organizations representing the thousands of safety net providers and programs that participate in the 340B program. The Coalition was created to assist providers with accessing and complying with the program while working with the federal government to improve implementation of the program.

The Coalition is generally in agreement with many of the suggestions made in the ANPRM with respect to implementation of the new authority for imposition of CMPs on manufacturers. We agree that the procedures for the Department of Health and Human Services Office of Inspector General's (OIG) imposition of CMPs codified at 42 CFR Part 1003 affords an appropriate and useful model for similar procedures in the 340B program. We think this model provides appropriate elements of Constitutional due process, administrative process and review that can and should be adopted for purposes of the 340B program. In fact, we would be in favor of utilizing the OIG for administration of the CMP program under the 340B statute, as we believe this function falls well within the statutory mission of the OIG. Moreover, the OIG's expertise would enhance the efficiency and speed of implementation of a new CMP structure.

We also agree with the ANPRM that, in determining whether a threshold has been reached for applying CMPs, the following factors should be considered: the amount and frequency of overcharges, the manufacturer's history of 340B compliance, the number of covered entities affected, and the reasonableness of the manufacturer's defense. We also agree that computation of a penalty may appropriately take into account the seven factors listed in section 7 of the ANPRM addressing penalty computation. We believe it would also be appropriate, and conducive to enhancement of 340B program compliance, if some portion of funds collected as CMPs from

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**Hemophilia Alliance; National Alliance of State and Territorial AIDS Directors; National Association of Children's Hospitals; National Association of Community Health Centers; National Association of Counties; National Association of Public Hospitals & Health Systems; National Family Planning & Reproductive Health Association; National Health Care for the Homeless Council; National Rural Health Association; Planned Parenthood Federation of America; Safety Net Hospitals for Pharmaceutical Access.**

manufacturers were directed to additional funding for the Office of Pharmacy Affairs (OPA) in carrying out its 340B program responsibilities, and a further portion were redirected to support the activities of the OIG in connection with 340B program integrity.

The Coalition strongly believes that an “instance” of manufacturer overcharging should be defined as a manufacturer overcharge on a per unit basis, rather than as overcharging in a given transaction. Thus, if a covered entity is overcharged for 100 units of a covered drug in a single transaction, this should be considered 100 instances of overcharging subject to a CMP. Because the statutory CMP authority provides for imposition of penalties *up to* \$5,000 per instance, a decision maker will have adequate discretion to adjust the penalty amounts, so that the total CMP imposed is not excessive when measured against the factors described in the ANPRM pertaining to penalty computation. We also believe that, when a covered entity has to purchase a covered outpatient drug at full price because the manufacturer has refused to sell the drug at a 340B price, the covered entity has been overcharged and CMPs should be applied.

Finally, the Coalition is in full agreement with the ANPRM insofar as it notes the importance of integrating the imposition of CMPs with other mechanisms for program integrity compliance and enforcement that are provided for in the Affordable Care Act. In particular, we believe that proceedings for imposition of CMPs should appropriately be initiated based on any of a wide variety of sources of information -- including spot audits, OPA calculations of 340B prices, administrative dispute resolution proceedings, and any other compliance mechanisms or other sources of information developed through the 340B program as enhanced by the recent legislation. The Coalition strongly opposes any suggestion that an aggrieved party must exhaust its remedies under the dispute resolution process before CMPs can be applied.

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The 340B Coalition appreciates the opportunity to submit the above comments. If you have any questions or need additional information, please do not hesitate to contact Staci LeBlanc at (202) 466-8960 or [sleblanc@ftlf.com](mailto:sleblanc@ftlf.com); Roger Schwartz at (202) 296-0158 or [rschwartz@nachc.org](mailto:rschwartz@nachc.org); Mike Glomb at (202) 466-8960 or [mglomb@feldesmantucker.com](mailto:mglomb@feldesmantucker.com); or Bill von Oehsen at (202) 872-6765 or [william.vonoehsen@snhpa.org](mailto:william.vonoehsen@snhpa.org).

Sincerely,

The 340B Coalition