



**Public Hospital Pharmacy Coalition**

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(A Coalition of the National Association of Public Hospitals and Health Systems)

February 17, 2005

The Honorable Michael O. Leavitt  
Secretary of Health and Human Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Leavitt:

We are writing on behalf of the Public Hospital Pharmacy Coalition (PHPC) and its member hospitals with respect to a recurring problem in administration of the Public Health Service 340B drug discount program.<sup>1</sup> For many years now, we have received reports of manufacturers and their suppliers refusing to sell certain drugs to 340B providers, ostensibly because there is no available supply of the drugs. This appears to be occurring quite frequently, for example, with respect to IVIG (intravenous immune globuline) products such as Polygam, Gamunex, and Carimune; but we have also received reports of similar shortages of other products. These product "shortages" arise, according to our information, because all available supplies of the drugs have been committed to other purchasers under commercial contracts, and because, according to the manufacturers, fulfilling these contractual obligations must take priority over making the drugs available at discounted 340B prices. So the drugs are, in fact, available to commercial and retail entities that contract directly with the manufacturers for supplies of their products, but are not available to 340B entities, despite the 340B pharmaceutical pricing agreements between the Department of Health and Human Services (HHS) and the manufacturers. We believe that this conduct on the part of manufacturers and their suppliers violates the spirit and clear legislative intent of the statutory provisions governing the 340B program. We therefore request that the Department of Health and Human Services (HHS) take appropriate action to address the problem, by prohibiting manufacturers from prioritizing the demands of commercial purchasers over the publicly-supported 340B providers that form our nation's healthcare "safety net."

In order to view this issue in its proper context, it is useful to revisit briefly the history of the 340B program. The genesis of the 340B program was an attempt to prevent pharmaceutical manufacturers from engaging in what the Committee on

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<sup>1</sup> PHPC represents virtually all of disproportionate hospitals participating in the 340B program.



**NATIONAL ASSOCIATION OF PUBLIC HOSPITALS & HEALTH SYSTEMS**

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Veterans' Affairs termed "gaming" strategies in dealing with the Medicaid Drug Rebate System.<sup>2</sup> When the Medicaid rebate program was instituted in 1990 to lower Medicaid's pharmaceutical costs, drug manufacturers initially responded by raising the prices they charged to other providers supported by federal, state and local taxpayers. Consequently, the purposes of the rebate law were being thwarted because the savings achieved through the Medicaid rebate program were being offset by increased federal and state spending in other programs. To correct this situation, Congress enacted sections 601 and 602 of the Veterans Health Care Act of 1992<sup>3</sup>, which added section 340B to the Public Health Service Act and amended Medicaid law to require manufacturers whose drugs are covered by Medicaid to enter into a pharmaceutical pricing agreement ("PPA") with the Secretary of HHS, obligating the manufacturers to comply with the drug discount provisions set forth in section 340B.

This legislative history is important to the present issue for two principal reasons. First, in enacting supplemental legislation, Congress indicated its clear intent that drug manufacturers should be prevented from "gaming" the legislative scheme with respect to drug rebates and discounts in publicly-supported programs and circumventing Congressional intent. Second, although the point may be more implicit than explicit in the words of the statute, there is no question that Congress intended 340B covered entities to have access to covered drugs at discounted prices, not simply to be entitled to theoretical discounts on drugs that are in fact not available for purchase.

As the Committee Report accompanying the 340B legislation made clear, the very purpose of giving covered entities access to price reductions was to "enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."<sup>4</sup> Plainly, the 340B program cannot assist covered entities to "stretch resources" if they are unable to actually obtain the discounted drugs that their patients need and must therefore resort to acquiring the drugs at higher prices outside the program. Just as plainly, the statutory directive that manufacturers agree to require only discounted payment for purchases of their products by covered entities, implicitly demands that the products must be made available for purchase at those prices. While the standard manufacturer PPA does not directly state that the manufacturer is obligated to assure that supplies of its products are available for purchase under the 340B program, surely the manufacturer's responsibility "to charge covered entities a price" for its products that is not in excess of the applicable 340B ceiling price must be read to include an implicit obligation to make the product available at the discounted price.<sup>5</sup>

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<sup>2</sup> See H.R. Rep. No. 102-384, 102<sup>nd</sup> Cong. 1<sup>st</sup> Sess. Part I. at 8.

<sup>3</sup> Veterans Health Care Act of 1992, Pub. L. No. 102 - 585, 106 Stat. 4943 (codified as amended at 42 U.S.C. § 256b (2002).

<sup>4</sup> H.R. Rept. No. 102-384 on Medicaid Drug Rebate Amendments of 1992, to accompany H.R. 2890 (Part 2). 102d Cong. 2d Sess. at 12.

<sup>5</sup> It is noteworthy, in addition, that the standard manufacturer PPA also includes, under the section defining Manufacturer's Responsibilities, the statement that a manufacturer "may, at its option, make the [340B

Any other reading places 340B providers in an untenable position clearly unintended by Congress. This is especially true with respect to disproportionate share hospitals that are barred under the 340B statute from purchasing 340B-covered drugs through a group purchasing organization (GPO), or any other group purchasing arrangement. Consequently, when an ordered 340B drug is unavailable due to a so-called "shortage" problem, the hospital is prohibited from buying the drug off its GPO contract, forcing it to pay retail prices. Thus, entirely contrary to the intent of Congress, 340B hospitals are actually financially disadvantaged by their participation in the program when seeking to purchase drugs in short supply. This can create significant financial burdens on the provider, or create a dangerous impediment to provision of patient care. For example, hospitals in the 340B program play a critical role in treating trauma victims and providing other complex care that depends on the availability of medications such as IVIG products. We have heard from a number of member hospitals that, in order to avoid compromising patient care, they have been forced to purchase IVIG products on the commercial market for as much as two or three times the 340B price to which they are properly entitled.

Manufacturers' failures to make available to covered entities the products for which manufacturers are obligated to charge discounted 340B prices thus circumvent the plain meaning of the 340B law, the PPAs entered into with the Secretary of HHS, and the intent of Congress in establishing the 340B program. Such circumvention threatens to undermine the beneficial purposes of the program and should not be permitted by the Secretary. We therefore ask that the current situation be corrected by the following actions:

- 1) Issuance of further program guidance to 340B participants, including manufacturers, clarifying that manufacturers' responsibilities under the program include making any of their products available to 340B covered entities as long as the given product exists in sufficient supply to be available for purchase by any other category of purchaser; and
- 2) Revision of the standard 340B pharmaceutical pricing agreement, including all existing PPAs, to expressly codify the implicit point that a manufacturer's responsibility under the PPA to charge covered entities no more than a specified price for a given product includes an obligation to make available the product for which the "capped" 340B price may be charged.

We appreciate your prompt attention to this matter, and hope that you will not hesitate to contact us if we can be of any assistance in further explaining the issues

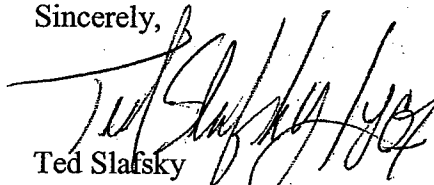
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price] available either directly to the covered entity" or to the entity's designated wholesaler. There is no provision for or contemplation of the 340B price not being "available" at all; yet there is obviously no way a manufacturer can "make available" the 340B price if the product to which the price relates is itself not available.

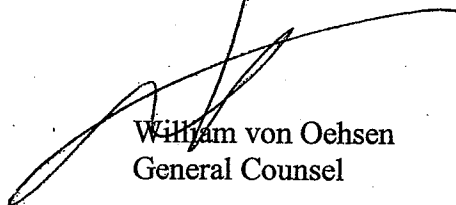
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discussed in this letter. If you have questions, please contact PHPC counsel, Edith Marshall, at (202) 872-6753.

Sincerely,



Ted Slafsky  
Executive Director



William von Oehsen  
General Counsel

Public Hospital Pharmacy Coalition

cc: Elizabeth Duke, Administrator, Health Resources Services Administration  
Daniel Levinson, Acting Inspector General, HHS