



## Public Hospital Pharmacy Coalition

[www.phpcrx.org](http://www.phpcrx.org)

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

May 16, 2006

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

Re: Formation of CMS/HRSA Working Group on 340B-Related Matters

Dear Secretary Leavitt:

I am writing on behalf of the Public Hospital Pharmacy Coalition (PHPC) regarding a matter that we regard as critically important to effective oversight of a federal drug discount program that is administered by the Health Resources and Services Administration (HRSA) under section 340B of the Public Health Service Act (hereinafter "the 340B program").<sup>1</sup> Established by Congress in 1992, the 340B program reduces the cost of outpatient pharmaceuticals for high-Medicaid disproportionate share hospitals, community health centers, and other safety net institutions serving large numbers of indigent patients. The purpose of this letter is to request your immediate assistance in forming a permanent working group composed of representatives of both the Centers for Medicare and Medicaid Services (CMS) and HRSA with sufficient authority to assure appropriate communication and coordination between the two agencies in areas where HRSA administration of the 340B program is dependent on CMS actions, determinations and/or policies.<sup>2</sup> PHPC is an organization of more than 350 public and private non-profit hospitals and health systems that rely on the 340B program to expand access to affordable drugs among the uninsured and other vulnerable patient populations in the United States.

The need to improve coordination between CMS and HRSA on 340B matters has been described in a long history of communications from both private advocacy groups and public officials, including representatives of your own Office of Inspector General (OIG), a senior

<sup>1</sup> Under the statute establishing the 340B program, drug manufacturers whose outpatient drugs are covered by Medicaid must enter into a formal agreement with the Secretary of the Department of Health and Human Services (Department) that requires the manufacturers to allow twelve different categories of "covered entities" to purchase drugs at deeply discounted prices for use by their patients. See 42 USC 256b(a). See also 42 USC 1396r-8(a)(5)(B).

<sup>2</sup> We do not suggest that there is no communication or coordination between CMS and HRSA at the present time, but rather that the broad range of CMS actions and functions that affect the 340B program require interagency communication and coordination of actions with sufficient regularity and at a sufficiently high level in the Department to achieve efficient administration of the 340B program.



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

1301 Pennsylvania Avenue, N.W. Suite 950, Washington, DC 20004, 202-585-0100, FAX 202-585-0101, [www.naph.org](http://www.naph.org)  
PHPC Counsel: Powers, Pyles, Sutter & Verville PC, 1875 Eye Street, NW 12th Floor, Washington, DC 20006,  
202-466-6550, FAX 202-785-1756, [www.ppsv.com](http://www.ppsv.com)

member of Congress, and witnesses at a recent Congressional hearing.<sup>3</sup> Indeed, some years ago, we were informed by both CMS and HRSA that the agencies had affirmative plans to actually form a working group of the type we suggest; but regrettably, it appears that these plans never reached fruition.

The linkage between 340B administration and the Medicaid and Medicare programs arises from overlapping provisions within the governing statutes. For example, the obligation of drug manufacturers to provide discounts to 340B covered entities is a statutory condition of Medicaid coverage for their drugs. The formula for computing 340B-discounted prices is derived directly from the statutory formula for determining Medicaid rebates and requires the utilization of data furnished to CMS under Section 1927 of the Medicaid statute. Whether a hospital qualifies for the 340B program depends in part on whether it is a disproportionate share hospital (DSH) under the Medicare statute and whether its DSH adjustment percentage calculated for Medicare reimbursement purposes meets a threshold prescribed in the 340B law. And in determining what facilities may be considered part of a hospital for purposes of buying and using 340B-priced drugs, HRSA applies Medicare cost report standards and principles. As a result of these overlapping authorities, there are numerous areas in which the 340B program has adopted, or is otherwise directly dependent on, standards, data, determinations or policies originating in Medicaid or Medicare administration.

Close communication and effective coordination between CMS and HRSA is therefore essential to proper administration of the 340B program. For example, because the 340B and Medicaid rebate programs both operate based on written agreements between the Department and manufacturers, the Department should assure contemporaneous execution of these agreements rather than rely on the current system of CMS and HRSA seeking signed contracts separately, thereby duplicating efforts. Moreover, information about compliance and enforcement matters needs to be shared between CMS and HRSA because fraud, routine errors and/or retroactive price adjustments in the Medicaid rebate program signal errors and inaccuracies in 340B pricing, and overcharges to covered entities for drugs under the 340B program can result in

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<sup>3</sup> The history of these communications spans a number of years. As early as the Fall of 2002, PHPC wrote to the Office of the Assistant Secretary for Planning and Evaluation about one of the many 340B program issues involving CMS and HRSA policies, and specifically recommended formation of a joint CMS/HRSA working group at that time. This recommendation was echoed in subsequent letters sent to both CMS and HRSA by the national organizations that represent the broader 340B community and advocate jointly through an organization called the 340B Coalition. The 340B Coalition advocated again formation of the joint working group by way of a letter sent to HRSA's Deputy Administrator in September 2003 and through another letter sent to the CMS Administrator in May of 2004. More recently, in a letter to you on September 1, 2005, Senate Finance Committee Chairman Charles Grassley similarly called for formation of a "task force" to address 340B-related issues involving CMS and HRSA functions. A month later, the OIG issued a report specifically identifying the need for CMS and HRSA to work together more closely and effectively on 340B program matters as a key programmatic deficiency that needs to be addressed. In December of 2005, PHPC's General Counsel testified in oversight hearings before a subcommittee of the House Committee on Energy and Commerce regarding the need for implementation of the joint working group concept, while a witness representing the OIG gave testimony confirming the need for enhanced communication and coordination between CMS and HRSA respecting 340B matters.

increased Medicaid expenditures by state and federal government. The integrity of 340B pricing hinges on the accuracy and reliability of CMS calculations and CMS-generated data elements, so HRSA needs to be fully apprised of factors that may cast the quality of those data and calculations into question. Additionally, resolution of questions relating to the 340B eligibility of hospital clinic and pharmacy sites may require information or input from the "fiscal intermediaries" under contract with CMS.

The above is by no means an exhaustive list of areas in which CMS and HRSA coordination is important to the 340B program. A change in the Medicare or Medicaid programs can affect the 340B program in significant ways that might not be anticipated by anyone unfamiliar with the 340B pricing and distribution system.<sup>4</sup> Plus, the advent of Medicare Part D has created new questions regarding how 340B rights and obligations should be addressed in contract negotiations between 340B pharmacies and Medicare prescription drug plans (PDPs), as well as how 340B discounts affect pricing arrangements between PDPs and manufacturers.

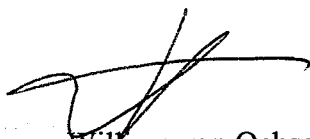
Accordingly, PHPC strongly believes that, while the 340B program falls within the sphere of HRSA responsibility, 340B administration is inextricably connected to CMS operations and, for this reason, cannot be performed properly without regular communication and a high degree of coordination between the two agencies. Realistically, without the support of an institutionalized interagency working group, CMS personnel, with neither duty assignments nor any significant degree of experience or familiarity with the 340B program, cannot be expected to take into account how the 340B program will be affected when engaged in Medicare and Medicaid decision making. Similarly HRSA officials responsible for the 340B program, lacking well-defined avenues for coordination with CMS, are in an unenviable position of being responsible for administration of a program over which they have insufficient control. For these reasons, we ask the Department to form a joint CMS/HRSA working group charged with identifying, inquiring into, and assuring appropriate communication and coordination within the many areas in which 340B and Medicare or Medicaid administration intersect. We believe that a working group of this type would significantly enhance 340B program administration, and would assist substantially in assuring effective achievement of the important goals underlying the 340B program.

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<sup>4</sup> For example, 340B providers have recently reported exacerbated difficulties in obtaining certain blood-derived products at 340B prices, which appear to be in part attributable to changes in physician reimbursement under Medicare. It also appears that Medicare changes regarding the significance of average sales price (ASP) have created an incentive on the part of manufacturers to modify their past drug distribution practices in a way that may diminish benefit of 340B pricing to qualified safety net providers.

Michael O. Leavitt, Secretary  
May 16, 2006  
Page 4 of 4

We would be pleased to meet with the Department to discuss our request in more detail. In the meantime, please do not hesitate to contact us at (202) 466-6550 if you have any questions regarding this letter.



William von Oehsen  
General Counsel

Sincerely,



Ted Slafsky  
Executive Director

cc: Mark McClellan, CMS  
Elizabeth Duke, HRSA  
Jim Mitchell, Office of Pharmacy Affairs