

THE 340B COALITION

May 21, 2004

VIA OVERNIGHT MAIL

Mark McClellan, M.D., Ph.D
Administrator
Centers for Medicare and Medicaid Services
Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for CMS/HRSA Working Group

Dear Administrator McClellan:

The 340B Coalition would like to pass along its congratulations on your recent confirmation as CMS Administrator. Prior to your appointment as Administrator, the 340B Coalition was working with your predecessor, Mr. Tom Scully, to establish an interagency working group comprised of representatives of CMS and HRSA to address a number of overlapping issues in the area of pharmaceutical pricing. The 340B Coalition represents sixteen national organizations whose members participate in a federal drug discount program established under section 340B of the Public Health Service Act. Because the 340B drug discount program intersects with both the Medicaid drug rebate program and the Medicare disproportionate share hospital (DSH) program in a number of significant areas, the Coalition feels strongly that a CMS/HRSA working group is needed to help coordinate the administration of these three federal programs. The purpose of this letter is to offer the Coalition's assistance in explaining the history and need for the proposed working group, and to ask for your leadership and support in working with HRSA to form the working group.

The 340B Coalition's recommendation that CMS and HRSA form a working group dates back to 2002 when the Public Hospital Pharmacy Coalition submitted comments on March 5, 2002 to the Assistant Secretary for Planning and Evaluation as part of Secretary Thompson's Regulatory Reform Initiative. On October 2, 2002, the 340B Coalition followed this up with a joint letter to the administrators of CMS and HRSA enumerating the issues requiring interagency coordination. We have enclosed copies of these written requests so that you and your staff can review the history and substance of the Coalition's recommendation.

The need for a CMS/HRSA working group is more pressing today than ever. There are a number of ways that the 340B program can lower drug expenditures for state Medicaid programs, so the proposed working group could help evaluate and advise states about these

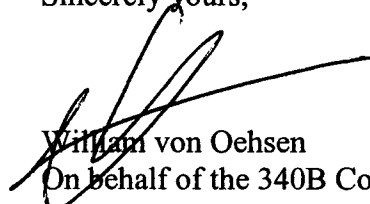
AIDS Action; AIDS Alliance for Children, Youth and Families; Communities Advocating Emergency AIDS Relief Coalition; Hemophilia Alliance, Inc.; National Alliance of State and Territorial AIDS Directors; National Association of Community Health Centers; National Association of Counties; National Association of People with AIDS; National Association of Public Hospitals & Health Systems; National Coalition for the Homeless; National Family Planning and Reproductive Health Association; National Health Care for the Homeless Council; National Hemophilia Foundation; National Rural Health Association; Planned Parenthood Federation of America, Inc.; Public Hospital Pharmacy Coalition

options. A working group is needed to help implement a couple of provisions within the Medicare Modernization Act: section 402 which will qualify hundreds of new hospitals (especially rural hospitals) for the 340B program by raising the Medicare DSH cap to 12 percent, and section 1002 which exempts 340B hospital's inpatient drug prices from the "best price" formula used to calculate Medicaid rebates. On the other hand, as state Medicaid agencies expand their rebate requests to include outpatient drugs administered by physicians and billed using 'J' codes, the risk that manufacturers will give two discounts on the same drug – one under the 340B program and the other in the form of a Medicaid rebate – increases dramatically. Both the Medicaid and 340B statutes direct the Secretary to develop a mechanism for avoiding this outcome. This is another area where coordination between CMS and HRSA is vital. There are many other issues that deserve the attention of a CMS/HRSA working group and, for a full description of these issues, we refer you to the attachments.

It is the Coalition's understanding that Mr. Scully was in the process of forming the requested CMS/HRSA working group shortly before his departure. Last year, one of the 340B Coalition members – the National Association of Public Hospitals and Health Systems (NAPH) – met with then-Administrator Scully and his assistant, Teresa Houser, to discuss a number of issues, including the need for CMS and HRSA to form such a working group. According to NAPH, Mr. Scully agreed that CMS should participate in the requested working group and asked Teresa Houser to follow up. These plans were never realized, however, due to the departure of Mr. Scully and the re-assignment of Ms. Houser to another department within HHS. The 340B Coalition is anxious that the apparent interest within CMS to collaborate with HRSA in forming an interagency working group not lose momentum. The Coalition stands ready to work with you in any way to achieve this important objective. Further delays could adversely affect administration of both the Medicaid and 340B programs.

The 340B Coalition would like to follow up this letter to discuss next steps. In the meantime, if you have any questions about this request, please contact Bill von Oehsen or Justin Hunter at (202) 466-6550.

Sincerely yours,



William von Oehsen
On behalf of the 340B Coalition

Enclosures

cc: Elizabeth Duke, Administrator, HRSA