

THE 340B COALITION

September 23, 2003

VIA FACSIMILE

Dr. Dennis Williams
Deputy Administrator, Health Resources and Services Administration
U.S. Department of Health and Human Services
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Re: HRSA/CMS Working Group

Dear Dr. Williams:

We are writing to follow-up on the presentation that you delivered on July 14, 2003 at the Seventh Annual 340B Coalition Conference held in Washington, D.C. During your presentation, you mentioned that the Health Resources and Services Administration (HRSA) still needs to work on a recommendation by the 340B Coalition to form a working group with the Centers for Medicare and Medicaid Services (CMS) in order to improve coordination between the two agencies on developing and implementing policies that affect both the 340B and Medicaid rebate programs. The 340B Coalition originally requested on August 7, 2002 that HRSA and CMS form such a working group, and we would like to take this opportunity to reiterate our request that the agencies establish the working group as soon as possible.

The most pressing reason for forming a joint working group is to help resolve what appears to be conflicting guidance on how covered entities should bill Medicaid for drugs purchased under the 340B drug discount program and administered by physicians or other professionals to Medicaid patients. The 340B Coalition submitted with its August 2002 letter a legal memorandum outlining how it believes this issue should be resolved based on existing 340B and Medicaid law. Continued government inaction will increase the risk that manufacturers may be asked to give two discounts on the same drug, especially in light of current efforts by CMS to encourage states to begin requesting rebates for physician-administered drugs. Congress explicitly directed the Secretary of Health and Human Services to develop a billing mechanism that would avoid this duplicate discount problem. The billing mechanism developed by HRSA almost ten years ago desperately needs refinement because its application to physician-administered drugs was never considered at the time and has caused significant confusion among 340B providers and state Medicaid agencies.

AIDS Action; AIDS Alliance for Children, Youth and Families; Communities Advocating Emergency AIDS Relief Coalition; The Hemophilia Alliance, Inc.; Human Rights Campaign; National Healthcare for the Homeless Council; The National Alliance of State and Territorial AIDS Directors; The National Association of Community Health Centers; The National Association of People with AIDS; The National Association of Public Hospitals & Health Systems; The National Coalition For The Homeless; The National Family Planning & Reproductive Health Association; The National Hemophilia Foundation; The Public Hospital Pharmacy Coalition; San Francisco AIDS Foundation

Another topic that the proposed working group could address relates to a Federal Register notice issued by CMS only a few weeks ago which, if implemented, will limit manufacturers' obligation to recalculate their Medicaid rebates. Because manufacturers rely on the same statutory formula for calculating the Medicaid rebate and 340B price for a given covered outpatient drug, we are concerned that a federal policy limiting industry's obligation to recalculate discounts under the rebate program would also apply to the 340B program, even though CMS' notice makes no mention of the 340B program. If a CMS/HRSA working group had been in place, the notice could have included a clarification describing how the notice applies to the 340B program which, in turn, would avoid the confusion with which the 340B community is currently responding to the notice.

There are other matters that could benefit from formation of a HRSA/CMS working group. For example, the working group could coordinate current and future efforts to recover overcharges by pharmaceutical manufacturers who fail to give their "best price" to the Medicaid and 340B programs as required by federal law. The working group could clarify the roles of HRSA and CMS in evaluating the eligibility of disproportionate share hospitals seeking to enroll in the 340B program, especially when hospitals dispute the Medicaid disproportionate share adjustment data that HRSA receives each quarter from CMS. The group could also develop jointly a policy clarifying the definition of a "covered outpatient drug" since it is our observation that application of this term in the Medicaid and 340B programs differs somewhat.

The 340B Coalition believes that the formation of a working group comprised of HRSA and CMS representatives will significantly benefit the 340B community and state Medicaid agencies by helping to eliminate inconsistent guidance and by facilitating cooperation between the agencies in fulfilling their overlapping administrative duties. We appreciate your remarks at the 340B conference acknowledging this need and request that HRSA take the lead in contacting CMS officials to initiate the formation of the working group. If the 340B Coalition can be of any assistance in this matter, please do not hesitate to contact Ted Slafsky or me at 202-466-6550.

Sincerely,



William von Oehsen
General Counsel
Public Hospital Pharmacy Coalition

cc: Jimmy Mitchell