

Congress of the United States
Washington, DC 20515

December 17, 2007

Elizabeth M. James Duke, Ph.D.
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
Parklawn Building – Room 14-05
5600 Fishers Lane
Rockville, MD 20857

Fax: 301/443-1246, Ph: 301/443-2216

RE: Guidelines for Children's Hospitals' Participation in the "340B" Outpatient Drug Discount Program

Dear Dr. Duke:

As supporters of federal policies that ensure the equitable treatment of children's hospitals, we are writing to encourage your expeditious publication in the *Federal Register* of final guidelines for children's hospitals to apply to participate in the Sec. 340B outpatient drug discount program, which the Health Resources and Services Administration (HRSA) administers through its Office of Pharmacy Affairs.

In Sec. 6004 of the Deficit Reduction Act (DRA) of 2005, enacted in February 2006, Congress directed the Department of Health and Human Services to permit independent children's hospitals to participate in the 340B program, provided that they could meet all of the requirements of "disproportionate share (DSH)" hospitals that currently participate, with the exception of their receiving Medicare DRG-based prospective payments.

This provision was championed by our late colleague, Representative Paul Gillmor, who recognized that the children's hospitals were excluded from participating in the 340B drug discount program as DSH hospitals, even though they are among the nation's leading providers of care to low-income patients. The single reason for this exclusion was that the law uses a definition of "disproportionate share hospital" that applies only to hospitals that receive Medicare DRG-based prospective payments. Independent children's hospitals were exempt from Medicare's prospective payment system when it was enacted in 1983 because they see few if any Medicare patients.

In July 2007, 17 months after the DRA's enactment, HRSA proposed for public comment draft guidelines that would permit children's hospitals to apply to participate in the 340B program. The agency said it would not implement final guidelines until after the September deadline for comment submission.

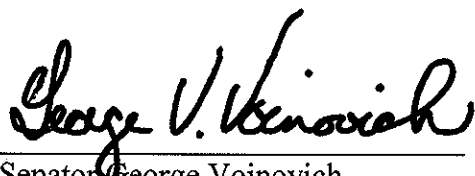
To date, nearly two-years since the law's enactment, HRSA has yet to issue final guidelines. As a consequence, children's hospitals and their patients continue to be arbitrarily excluded from the benefits of low drug prices under the 340B program. The continued delay deprives children's hospitals of an estimated, average annual savings of about \$1 million, according to the National Association of Children's Hospitals.

We are eager to see the 2006 change in law implemented as soon as possible. It was the clear intent of Congress to end the de facto exclusion of children's hospitals from the 340B program. Their exclusion has denied the federal government the opportunity to reduce the cost of Medicaid payment for pharmaceutical products and has denied children's hospitals and their payers the opportunity to reduce the costs of their care.

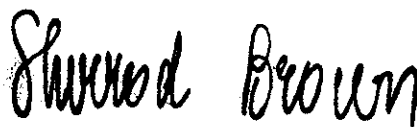
We urge you to issue final guidelines in time to allow the children's hospitals to apply for participation in 340B for the next quarter, which begins in January 2008. Were it not possible to issue final guidelines, for whatever reason, we ask that you issue interim guidelines so that the hospitals may begin to apply and participate in the program without further delay.

Thank you for your consideration of our request for expedited issuance of the final guidelines and equally expeditious implementation of the law.

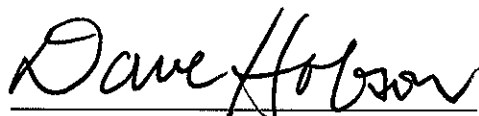
Sincerely,



Senator George Voinovich



Senator Sherrod Brown



Congressman Dave Hobson



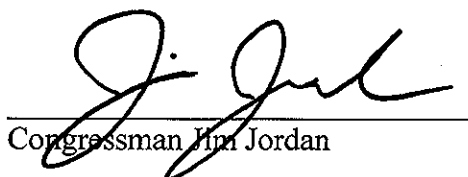
Congressman Tim Ryan



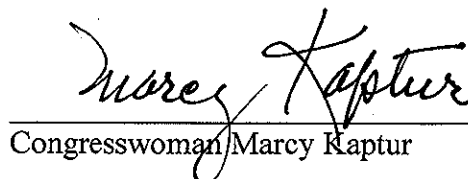
Congressman Steve Chabot



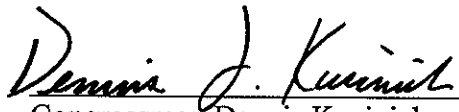
Congresswoman Stephanie Tubbs Jones



Congressman Jim Jordan



Congresswoman Marcy Kaptur


Congressman Dennis Kucinich

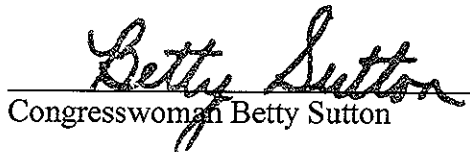

Congressman Steve LaTourette


Congresswoman Deborah Pryce


Congressman Ralph Regula


Congresswoman Jean Schmidt


Congressman Zach Space


Congresswoman Betty Sutton


Congressman Pat Tiberi


Congressman Mike Turner


Congressman Charlie Wilson

cc: Jimmy Mitchell, Office of Pharmacy Affairs, HRSA