

THE 340B COALITION

February 10, 2014

The Honorable Kathleen Sebelius, Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave S.W.
Washington, D.C. 20201

Subject: Implementation of 340B Manufacturer Program Integrity Provisions

Dear Secretary Sebelius:

The 340B Coalition is writing to provide our views regarding the use of the additional funds recently provided to the Health Resources and Services Administration (HRSA) under the Consolidated Appropriations Act of 2014. The monies are to be used by HRSA to address compliance concerns raised by both OIG and GAO.

The 340B Coalition represents thousands of safety-net health centers, hospitals, state AIDS Drug Assistance Programs, and specialty clinics that qualify as covered entities under HRSA's 340B drug discount program. We strongly urge that the nearly \$6 million in additional 2014 funding provided for 340B program integrity efforts be used first and foremost by the Office of Pharmacy Affairs (OPA) to implement recommendations in the October 2005 OIG report titled "Deficiencies in the Oversight of the 340B Drug Pricing Program" as well as the July 2006 OIG report titled "Review of 340B Prices." Many of these recommendations were subsequently enacted in the Affordable Care Act (ACA), but have not yet been implemented. These include:

- giving covered entities access to federally verified ceiling process via a secure page on the OPA website;
- selective audits of manufacturers and wholesalers;
- a system to verify the accuracy of 340B ceiling prices calculated by manufacturers, including a spot check of sales transactions;
- procedures for manufacturers to issue refunds to covered entities for overcharges, including an explanation for how the overcharge occurred and how the refund was calculated; and,
- procedures for manufacturers to give covered entities refunds in cases where discounts manufacturers gave to other purchasers had the effect of lowering the 340B ceiling price.

We ask that you give strong consideration to our recommendations for enhanced program integrity. We also urge that these integrity provisions be addressed in the comprehensive 340B regulation that HRSA is expected to release this year. As organizations that represent providers who work with the 340B program every day, we are deeply committed to the integrity of the program. These changes and modifications will help enhance the integrity of the program and help us better serve our patients. Implementation of these recommendations would go a long way toward achieving these goals. Thank you for giving us an opportunity to express our views. We look forward to our continued work together to ensure that the 340B program remains a strong program that supports the most vulnerable populations.

Sincerely,

The 340B Coalition

cc: Mary Wakefield, HRSA Administrator
Caya Lewis, Counselor to the Secretary
Jim Esquea, Assistant Secretary for Legislation
Sonja Nesbit, Deputy Assistant Secretary for Legislation
Krista Pedley, HRSA Office of Pharmacy Affairs