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April 3, 2013

Krista Pedley, PharmD, MS
CDR, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 10C-03
Rockville, MD 20857

RE: Statutory Prohibition on Group Purchasing Organization Participation

Dear Commander Pedley:

On behalf of our nearly 2,000 member hospitals that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the opportunity to share our concerns about the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs' February 7, 2013 notice regarding the 340B program group purchasing organization (GPO) prohibition. The 340B program is critical to improving access to needed pharmaceutical services for qualified safety-net hospitals and other providers by obtaining lower-cost drugs, provided in outpatient settings, for poor and underserved patients. As we discussed with you at our March 14 meeting, we remain very concerned that the policy changes outlined in the February 7 notice could threaten hospitals' access to this crucial program.

The HRSA notice clarifies 340B program policy regarding the statutory prohibition against obtaining outpatient drugs through a GPO. The statutory GPO prohibition applies to disproportionate share hospitals, children's hospitals and free-standing cancer hospitals participating in the 340B program. The guidance focuses on: the scope of the GPO prohibition and certification of compliance; outpatient clinic sites and areas of the hospital where the GPO prohibition applies; the GPO prohibition compliance date; compliance through "replenishment" strategies; and sanctions for violation of the GPO prohibition. The notice requires that 340B hospitals, subject to the GPO prohibition, comply with the new guidance by April 7.

The AHA believes that the notice poses a significant departure from previous HRSA guidance regarding the statutory GPO prohibition, in particular, HRSA guidance on hospital pharmaceutical inventory management models and practices. In addition, we believe HRSA should have adhered to the requirements of the *Administrative Procedures Act* and allowed for public notice and comment regarding these policy changes. These 340B hospitals were given



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only 60 days (until April 7, 2013) to change complex hospital procedures to meet the new HRSA policies or risk being expelled from the 340B program.

We have heard from many 340B hospitals affected by the notice that they face numerous challenges in modifying existing inventory management practices by April 7 to comply with HRSA's new GPO guidance. Such challenges include working with vendors to adapt or change current inventory management systems, working with wholesalers to establish new accounts, and working to ensure sufficient time to train staff and audit their internal processes. The AHA has encouraged our 340B hospital members subject to the GPO prohibition to communicate directly with you about their challenges and provide a plan of action and timeline for coming into compliance with the new GPO policy changes.

The AHA strongly urges that HRSA delay the compliance date by at least six months to allow sufficient time for affected hospitals to make the necessary modifications to their existing inventory management practices as required by the new GPO guidance. This delay would allow hospitals time to work with their vendors and wholesalers to address the many process and procedural challenges brought on by the February 7 notice, to properly train staff to manage the new processes, and to ensure that these revised internal processes are working well. We further recommend that HRSA continue to work with affected 340B hospitals to provide guidance and education on the GPO compliance issues.

We believe the 340B program is critical to ensuring access to pharmaceuticals for safety-net hospitals and the patients and communities they serve. We look forward to working with you and your staff on all issues regarding the 340B program.

Thank you for your attention to this request. If you have any questions, please feel free to contact me or Molly Collins Offner, director of policy development, at (202) 626-2326 or mcollins@aha.org, or Aimee Hartlage Kuhlman, senior associate director of federal relations, at (202) 626-2291 or ahartlage@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President