Congress of the United States

Washington, DC 20510

January 31, 2013

Mary K. Wakefield, BSN, MS, PhD
Administrator
Health Resources and Services Administration
Parklawn Building
5600 Fisher's Lane, Room 14-05
Rockville, MD 20857

Dear Administrator Wakefield:

We write to you to obtain more information about the audits that the Health Resources and Services Administration (HRSA) recently conducted to certify that covered entities are still eligible for the 340B Drug Pricing Program (340B Program). We support HRSA's renewed interest in oversight of the 340B Program, but also support greater transparency to ensure that HRSA's efforts are as effective as possible.

In September 2011, the Government Accountability Office (GAO) issued a report that notes HRSA's inadequate oversight of the 340B program. Specifically, GAO reported "…the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater, in part because they serve both 340B and non-340B eligible patients."[1] Part of the oversight inadequacy is due to the fact that prior to 2012, HRSA "never conducted an audit to determine whether program violations have occurred."[2] Additionally, for 20 years HRSA failed to engage in a recertification process for covered entities. By its inaction, HRSA essentially turned a blind eye to entities who no longer should have been participating in the 340B program, allowing them to improperly reap the benefits of deeply discounted 340B drugs. Only last year did HRSA finally begin to ensure that participants continued to be eligible.

On July 9, 2012, Krista Pedley, Director of the Office of Pharmacy Affairs (OPA) under HRSA, spoke at the Annual 340B Coalition Conference regarding upcoming audits. We applaud HRSA's stance, which Commander Pedley articulated at the conference, of "throwing out a word of caution" to covered entities who employ multiple contract pharmacies and outpatient clinics to ensure compliance with the program.[3] Likewise, we commend HRSA for completing the 2012 recertification process of over 3,800 hospitals.

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[1] GAO September 2011 Report to Congress; http://www.gao.gov/assets/330/323702.pdf
[2] *Id.*
[3] *The Pink Sheet,* July 16, 2012

However, it is our understanding that the 2012 recertification process resulted in the decertification of "about 250" covered entities from participation in the 340B program.[4] We also understand that HRSA has initiated on-site audits of 45 covered entities and six targeted audits. HRSA's decision to begin these audits and conduct these recertifications is critically important to ensure proper oversight of the 340B program. To gain a better understanding of HRSA's audit process, we ask that you please provide answers to the following questions in writing by February 14, 2013:

1. Please provide the criteria HRSA used in selecting the covered entities for targeted audits.

2. Please provide a list of all 51 covered entities (45 random and six targeted) HRSA has selected for these audits.

3. What is HRSA's timeframe for completing all 51 audits?

4. Please provide copies of the questions asked and document requests made by HRSA of each covered entity.

5. Please provide a detailed description of:

    a. The status of each audit, including whether additional information needs to be obtained and what such outstanding information is;
    b. The findings of each audit as each one is completed;
    c. What, if any, corrective action must be taken by HRSA in ensuring the proper compliance of each audited covered entity.

6. In light of the 2012 recertification process, please provide the list of all decertified covered entities. In this list, please provide:

    a. The cause for decertification;
    b. The length of time each covered entity was ineligible before being decertified;
    c. Whether these covered entities were continuing to purchase at 340B prices from manufacturers while they should have been ineligible.

7. What are HRSA's plans for recoupment of any 340B discounts achieved by covered entities during periods of ineligibility?

8. Please describe what, if any, legal action will be taken against those covered entities who continued to receive the 340B discount when they were ineligible for the program. If no legal action will be taken against covered entities who continued to receive 340B discounts when they were ineligible to do so, please explain why not.

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[4] *Id.*

Maintaining the integrity of the 340B program is of the upmost importance, and we trust that you share our concerns. If you have any questions regarding this request, please contact Heidi Stirrup with Chairman Pitts of the House Energy & Commerce Health Subcommittee at (202) 225-3641; Erika Smith with the Senate Committee on the Judiciary at (202) 224-5225; Hayden Rhudy with the Senate Finance Committee at (202) 224-5251; or Melissa Pfaff with the Senate Health, Education, Labor and Pensions Committee at (202) 224-0751.

Sincerely,

Lamar Alexander
U.S. Senator

Joe Pitts
Member of Congress

Orrin G. Hatch
U.S. Senator

Michael B. Enzi
U.S. Senator

Charles E. Grassley
U.S. Senator

Bill Cassidy
Member of Congress

cc: Chairman Harkin
Senate Health, Education, Labor, and Pensions Committee

cc: Ranking Member Frank Pallone
Health Subcommittee
House Energy and Commerce Committee

cc: Chairman Max Baucus
Senate Finance Committee

cc: Chairman Patrick Leahy
Senate Committee on the Judiciary