

Congress of the United States

Washington, D.C. 20515

September 22, 2011

Mary K. Wakefield, PhD, RN
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fisher's Lane
Rockville, MD 20857

Dear Administrator Wakefield:

We are writing to you in our roles as Chairman of Energy and Commerce and Ranking Members of the Senate Finance, Health, Education, Labor and Pensions (HELP), and Judiciary Committees. Specifically, we are interested in understanding the actions that the Health Resources and Services Administration (HRSA) has taken to oversee the administration and effectiveness of the 340B Drug Pricing Program (340B program). We raise this issue as an area of mutual concern given our collective mandate to protect beneficiaries of Federal health care programs.

The 340B program, as established in the Public Health Service Act (PHSA), is a voluntary program that ensures that certain providers within our nation's health care safety net (covered entities) have access to outpatient drugs at or below statutorily defined ceiling prices.¹ These covered entity providers are also able to generate revenue under the 340B program through third-party reimbursements from patients with private insurance coverage. Given these benefits, it is not surprising that participation in the 340B program has nearly doubled in the last decade.²

As the 340B program continues to evolve, it is critical that HRSA provides diligent oversight of both the program and its participants. Adequate monitoring by HRSA is fundamental to ensuring that the 340B program meets its goal of providing affordable outpatient drugs to patients of covered entities. To better understand HRSA's oversight efforts to date, please provide answers to the following inquiries in writing by October 7, 2011:

1. Provide a detailed description of HRSA's past efforts and future plans to conduct oversight of the 340B program. In addition to this general overview, please include the following information:

¹ 42 U.S.C. § 256b.

² According to the HRSA covered entity database, the number of covered entities has grown from 8,605 in 2001 to 16,572 in 2011.

- a. A breakdown of the number and type of audits performed by HRSA with respect to the 340B program since 1992. Please provide the protocols, results, and subsequent corrective action plans for each.
 - b. Copies of protocols and any strategic planning documents related to future audits of the 340B program planned by HRSA and/or its contractors or partners.
2. Describe in detail the process by which HRSA verifies eligibility of both covered entities and drug manufacturers for participation in the 340B program. Please include the frequency of such eligibility verification processes.
3. Describe in detail the process by which HRSA performs ongoing compliance oversight of covered entities and drug manufacturers after they are approved for participation in the 340B program. Please include the frequency of such compliance processes.
4. For the past five fiscal years, please provide an itemized breakdown of all appropriations, obligations, and expenditures requested and received as part of HRSA's annual budget for funds dedicated to oversight of the 340B program including, but not limited to, covered entity verification and compliance among all program participants.
5. In a June 2011 Department of Health and Human Services' Office of Inspector General (OIG) report, the OIG reported that 14 states currently conduct postpay audits of covered entities who receive 340B-purchased drugs.^[1] Is HRSA aware of these audits? If yes, what processes does HRSA have in place to enforce Section 340B(5) to ensure that duplicate discounts are not provided?
6. Describe in detail what processes HRSA has in place to work with the Centers for Medicare and Medicaid Services (CMS) to enforce Section 340B(5) of the statute regarding duplicate discounts?
7. Is HRSA notified of each dispute or payment discrepancy between covered entities and drug manufacturers? If a dispute is resolved, are the covered entity and manufacturer required to report such dispute and resolution? What action has HRSA taken to resolve future disputes based on lessons learned from past disputes?
8. For the past five fiscal years, provide an itemized breakdown of the percentage and dollar amount of HRSA's annual budget that goes towards covered entity outreach, including, but not limited to, HRSA officials' participation in conferences, seminars, or events with covered entities.

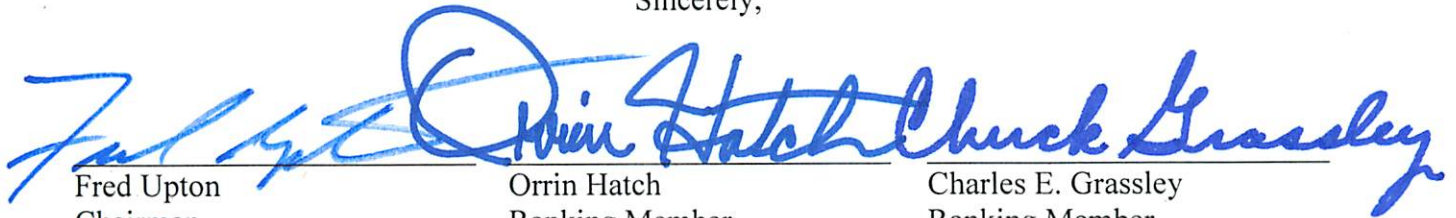
Maintaining the integrity of the 340B program is of the utmost importance, and we trust that you share our concerns. If you have any questions regarding this request, please contact

^[1] HHS Office of Inspector General, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, (Washington, D.C.: 2011).

Letter to Mary K. Wakefield, PhD, RN
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Monica Popp with the Energy and Commerce Committee at (202) 225-3641 or Erika Smith with the Senate Judiciary Committee at (202) 224-5225.

Sincerely,



Fred Upton
Chairman
Committee on Energy
and Commerce

Orrin Hatch
Ranking Member
Committee on Finance

Charles E. Grassley
Ranking Member
Committee on the Judiciary

cc: The Honorable Henry A. Waxman, Ranking Member
Committee on Energy and Commerce

The Honorable Max Baucus, Chairman
Committee on Finance

The Honorable Patrick J. Leahy, Chairman
Committee on the Judiciary