



January 11, 2011

Dr. Mary Wakefield, R.N., PhD.
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Room 14-05 Parklawn Building
Rockville, MD 20857

Re: Denial of 340B Retroactive Discounts to Newly Enrolled Rural Hospitals

Dear Dr. Wakefield:

On behalf of the members of the American Hospital Association (AHA), the National Rural Health Association (NRHA) and Safety Net Hospitals for Pharmaceutical Access (SNHPA), we would like to express our concerns over guidance issued by the Office of Pharmacy Affairs (OPA) regarding access to retroactive discounts for newly enrolled covered entities in the 340B drug discount program. We represent hospitals participating in the federal 340B drug discount program, including many hospitals that are newly eligible for the program. We are troubled by guidance on OPA's "frequently asked questions" web page stating that newly enrolled entities made eligible for the program by the Patient Protection and Affordable Care Act (PPACA) are not eligible for retroactive rebates dating back to January 1, 2010. We object to this guidance because it directly contradicts both the language of PPACA as well as past guidance issued by the Health Resources and Services Administration (HRSA).

Background

Section 7101 of PPACA extended 340B eligibility for the first time to certain cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals.ⁱ Section 7101 states that these changes "shall take effect on or after January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010."ⁱⁱ In response to the question of whether newly enrolled entities are entitled to retroactive rebates back to January 1, 2010, the OPA's FAQ stated:

"No. As a general rule, the Office of Pharmacy Affairs does not consider any entity eligible for 340B pricing until the entity is fully enrolled, assigned a 340B identification number and listed in the 340B database. A newly enrolled covered entity's benefit starts the day the covered entity is listed on the database as eligible."ⁱⁱⁱ

We object to this guidance because it conflicts with both the language of PPACA and past guidance issued by HRSA.

Conflict with Plain Meaning of PPACA

Section 7101 of PPACA makes clear that the expansion of 340B eligibility to new categories of hospitals “shall apply to drugs purchased on or after January 1, 2010.”^{iv} The plain meaning of this language is clear and there is no ambiguity. The statute states that the amendments apply to drugs purchased on January 1, 2010, therefore Congress intended for the newly added hospitals to be able to purchase drugs at the 340B discount rate on January 1, 2010. Congress was well aware that the newly added entities would need to show the government that they qualify for 340B pricing before they could actually purchase drugs at 340B discounts. Knowing that this process would take time, Congress made clear that the pricing would be available before that process was complete – on January 1, 2010. Our concern is that the FAQ runs counter to the statutory language and Congressional intent of making the amendments apply to drugs purchased on January 1, 2010, as the FAQ makes it impossible for the newly added entities to access drugs at the 340B pricing as of January 1, 2010, thereby rendering that statutory language meaningless.

The drug industry itself recognized the clear Congressional intent of the provision. Prior to OPA’s announcement denying retroactive discounts, some drug manufacturers were under the impression that PPACA required them to provide retroactive discounts dating back to January 1, 2010 for those newly eligible entities that enrolled in the program. Bristol-Myers Squibb (BMS) said in its third quarter earnings report filed with the U.S. Securities and Exchange Commission (SEC) that it is “required” to extend retroactive 340B discounts for rural entities.^v Some manufacturers even reserved funds in their budgets to pay for retroactive rebates. In a telephone conference call to report third quarter earnings, officials at Eli Lilly and Co. said HRSA’s unexpected announcement allowed them to return \$40 million in revenues to the company’s balance sheet for 2010.^{vi} The Biotechnology Industry Organization (BIO) also acknowledged that PPACA called for retroactive discounts. In comments submitted to HRSA on September 3, 2010, regarding implementation of PPACA, BIO noted that if HRSA were to permit retroactive rebates, it should do so only if newly eligible covered entities met the same criteria HRSA required of children’s hospitals when they became eligible for 340B in 2009.^{vii} BIO made clear to HRSA that the pharmaceutical industry was ready and willing to provide retroactive discounts under these conditions.

We understand that the newly eligible hospitals only qualify for the refunds we are seeking if they can demonstrate that they met the 340B eligibility criteria during the retroactive period. However, the rural hospitals now eligible for the program face fewer obstacles to qualify for retroactivity than children’s hospitals faced in 2009, providing even stronger reasons for OPA to recognize the entities’ right to retroactive relief. HRSA’s 2009 final rule allowing children’s hospital enrollment stated that a children’s hospital could only request retroactive discounts to the extent that it “satisfied all requirements for participation in the 340B program back to the date discounts are requested.”^{viii} This posed great difficulty for many children’s hospitals because the program prohibited children’s hospitals from purchasing drugs through a group purchasing agreement (GPO). Because many children’s hospitals had been using a GPO prior to their dates of enrollment, they were not in compliance with all program requirements and thus were not able to request retroactive discounts. In contrast, many of the newly eligible rural entities, including critical access hospitals, rural referral centers and sole community hospitals, are not subject to a GPO prohibition.^{ix} Therefore, rural hospitals are much more likely to have

been meeting the 340B program requirements prior to their date of enrollment than children's hospitals.

Conflict with Prior HRSA Guidance

OPA's FAQ also conflicts with prior guidance issued by HRSA when other covered entities have become eligible for the program. Since the beginning of 340B, HRSA and OPA have set a precedent for providing retroactive discounts. The Veterans Health Care Act of 1992 (VHCA), the 340B program's governing statute, enacted section 340B of the Public Health Service Act (PHSA).^x VHCA said that the Secretary of the Department of Health and Human Services (HHS) must enter into agreements with manufacturers to provide discounted prices for "covered drugs purchased by a covered entity *on or after the first day of the first month that begins after November 4, 1992.*"^{xi} When HRSA published a Federal Register Notice in May 1993 to implement the 340B program, it said, "Agreements signed after that date [December 1, 1992] are effective for purchases of covered outpatient drugs *retroactive to December 1, 1992*"^{xii} Although HRSA has a clear history of recognizing retroactive rebates for newly enrolled 340B covered entities, OPA's guidance contains a puzzling statement that, as a general rule, it will not make discounts retroactive.

OPA's guidance is also inconsistent with the position it took when children's hospitals began to enroll in the 340B program last year. The Deficit Reduction Act of 2005 (DRA) made children's hospitals eligible for 340B discounts.^{xiii} Like PPACA, the DRA made the change to the 340B program effective retroactively, in the case of children's hospitals going back to the date of the DRA's enactment, February 8, 2006.^{xiv} HRSA honored Congressional intent to make the hospitals' enrollment retroactive when it implemented the new addition to the program. In a final rule published on September 1, 2009, HRSA said that "once children's hospitals are admitted to the 340B Program and listed on the Covered Entity Database, they are eligible for 340B drug pricing back to February 8, 2006."^{xv} We do not understand why OPA allowed retroactivity for children's hospitals last year but will not do so now for the rural entities made eligible by PPACA.

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OPA's denial of retroactive discounts to rural hospitals now enrolled in the 340B program conflicts with both the language of PPACA and past guidance issued by HRSA. We ask that OPA revise its guidance to advise newly eligible entities that have enrolled in 340B that they are entitled to retroactive rebates if they meet the same criteria OPA required of children's hospitals when they enrolled in the program last year. Please contact William von Oehsen at william.vonoehsen@snhpa.org or 202-872-6765 if you have any questions on this issue.

Sincerely,

American Hospital Association
National Rural Health Association
Safety Net Hospitals for Pharmaceutical Access

cc: Krista Pedley, Director, Office of Pharmacy Affairs

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- ⁱ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101(a) (2010).
- ⁱⁱ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101(e)(1) (2010).
- ⁱⁱⁱ http://answers.hrsa.gov/cgi-bin/hrsa.cfg/php/enduser/std_adp.php?p_faqid=2036&p_created=1284994818&p_sid=2bAz1sfk&p_accessibility=0&p_redirect=&p_srch=&p_lva=&p_sp=cF9zcmNoPSZwX3NvcnRfYnk9JnBfZ3JpZH NvcnQ9JnBfcm93X2NudD04MSw4MSZwX3Byb2RzPSZwX2NhdHM9NDkmcF9wdj0mcF9jdj0xLjQ5JnBfc2Vhc mNoX3R5cGU9YW5zd2Vycy5zZWYyY2hfbmwmcF9wYWdlPTE!&p_li=&p_topview=1.
- ^{iv} Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101(e)(1) (2010).
- ^v <http://www.gurufocus.com/StockLink.php?type=sec&symbol=BMJ&date=2010-10-26&report=10-Q>.
- ^{vi} <http://www.shareholder.com/visitors/event/build2/mediapresentation.cfm?companyid=LLY&mediaid=44293&mediauserid=4797961&TID=1043808152:a8e087e0485b45d31213857743e88c73&popupcheck=0&shexp=201010211451&shkey=d3ec7fad6dba4ce0f9222c769cd53e9f&player=1>.
- ^{vii} Letter from Laurel Todd, Managing Director, Reimbursement and Health Policy, Biotechnology Industry Organization, to Commander Krista Pedley, Director, Office of Pharmacy Affairs, (Sept. 3, 2010), *available at* <http://bio.org/healthcare/medicare/20101119b.pdf>.
- ^{viii} Final Notice Regarding 340B Drug Pricing Program—Children’s Hospitals, 74 Fed. Reg. 45206, 45211 (Sept. 1, 2009).
- ^{ix} See Health Care and Education Affordability Reconciliation Act, Pub. L. No. 111-152, § 2302(1)(C)(i).
- ^x Veterans Health Care Act, Pub. L. No. 102-585, §§ 601-603 (1992).
- ^{xi} Veterans Health Care Act, Pub. L. No. 102-585, § 602 (1992) (emphasis added).
- ^{xii} Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 50 Fed. Reg. 25110 (May 13, 1994) (emphasis added).
- ^{xiii} Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6004 (2005).
- ^{xiv} Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6004(b) (2005).
- ^{xv} Final Notice Regarding 340B Drug Pricing Program—Children’s Hospitals, 74 Fed. Reg. 45206, 45211 (Sept. 1, 2009).