



## **SNHPA's Regulatory Priorities for Obama Administration**

### **Stop Final Publication of New Patient Definition Standards for 340B Program**

On January 12, 2007, the Health Resources and Services Administration (HRSA) released proposed guidelines that would create a new definition of "patient" for purposes of the Public Health Service 340B drug discount program. The entire 340B safety net community – including disproportionate share (DSH) hospitals, community health centers, hemophilia treatment centers, etc. – are opposed to HRSA's proposed changes on the grounds that they would adversely alter the current workable standards by making them unnecessarily burdensome and restrictive. They are too complicated for pharmacists to implement and would ultimately strip many vulnerable populations of access to affordable medications.

Under the proposed guidelines, before deciding whether to fill a patient's prescription with drugs purchased under 340B, a pharmacist would need to know a number of significant and complex items not readily available through pharmacy point-of-sale systems: (1) the prescriber's relationship to the hospital; (2) whether the hospital maintains records that document the services and illness/condition resulting in the prescription; (3) whether the services were rendered at the hospital or at a provider-based site of the hospital; (4) the ownership and location of the records; (5) whether a physician employed by or under contract with the hospital executed a proper referral of the patient to a non-hospital prescriber; and (6) whether the patient will return to the hospital within 12 months of such a referral.

Both the House and Senate FY 2009 Department of Health and Human Services (HHS) Appropriations Subcommittee reports express concern with the proposal and encourage HRSA to work with 340B providers more closely. Towards that end, the 340B provider community has submitted to HRSA an alternative proposal that achieves a more reasonable balance between protecting against potential abuses and furthering the original purpose of the program.

### **Finalize Pending Childrens Hospitals and Contract Pharmacy Guidelines**

At the same time, publication of two other HRSA notices – one governing participation by childrens hospitals and the other allowing the use of multiple contract pharmacies – are long overdue. SNHPA was disappointed that those guidelines were not finally adopted before the end of the Bush Administration, and encourages the new HRSA administrator to move forward quickly with their adoption.

### **Revisit Other 340B Policies That Create Undue Burden for Safety Net Providers**

Program participation has grown increasingly difficult over the past eight years due to several HRSA policies that are based on unnecessarily legalistic and restrictive interpretations of the 340B statute. Examples include the following:

- With respect to the 340B prohibition against obtaining outpatient drugs through a group purchasing organization (GPO), HRSA has traditionally recognized certain common sense exceptions as long as the GPO drugs used on an outpatient basis are subsequently replaced with non-GPO inventory as a way to "cure" what would otherwise be a violation of the law. DSH hospitals have recently been told that this stock replacement approach to complying with the GPO exclusion is impermissible.



- When a hospital seeks to enroll a new site into the 340B program – because it has either built or acquired a new hospital facility – it must certify to HRSA that the costs of the new site are reimbursable on the hospital’s Medicare cost report. Over the past few years, HRSA adopted the position that the costs must be reimbursable on a *filed* cost report thereby delaying enrollment of new DSH sites up to twenty months.
- Under the current 340B definition of patient, an individual is only eligible to receive 340B drugs if he or she receives services from a professional employed by, under contract with or in other arrangements with the covered entity. Hospitals that treat patients via “other arrangements,” i.e., by indirect rather than direct contracts with professionals, are increasingly being accused of diversion.

### **Need for Greater Cooperation between CMS and HRSA**

SNHPA asks that the Obama Administration encourage the Centers for Medicare and Medicaid Services (CMS) to cooperate with HRSA on issues that affect 340B covered entities. Rather than embrace Congressional intent to lower the cost of drugs for safety net providers, CMS has operated from a different understanding of the program’s purpose, namely, to reduce Medicare and Medicaid expenditures. For example, with respect to 340B drugs administered by physicians in hospital outpatient settings, CMS has interpreted a provision in the Deficit Reduction Act of 2005 in a manner that requires DSH hospitals to pass their 340B discounts to Medicaid. And in the hospital outpatient prospective payment system (HOPPS) regulations issued by CMS in November 2008, CMS suggested that 340B hospitals be targeted for lower Medicare Part B reimbursement. The former policy is currently being challenged in court by SNHPA and a member hospital, and the latter policy has triggered a wave of comments from the hospital community, manufacturers, and other stakeholders opposing CMS’s suggestion. In addition, CMS has been slow in taking affirmative action that would facilitate Part D participation of 340B pharmacies and/or protect against Part D plans ratcheting down payment rates to 340B pharmacies.

To remedy this issue, SNHPA recommends either establishing a permanent HRSA-CMS working group to collaborate on matters involving overlapping jurisdiction of the two agencies or that 340B administration be elevated within HHS to a level above both HRSA and CMS.

### **340B Program Reform Legislation**

In the 110<sup>th</sup> Congress, legislation was introduced (HR 2606/S. 1376) that would establish measures to improve overall administration and enforcement of the 340B program. For example, the Secretary of HHS would be directed (1) to implement various measures to improve compliance by both manufacturers and covered entities and (2) to establish regulations to resolve disputes and allow easier recovery of overpayments by covered entities. The legislation would also extend 340B pricing to hospital inpatient drugs and add children’s hospitals and certain rural hospitals as covered entities.

In addition, SNHPA strongly believes that Congress should fully fund administration of the 340B program and, towards that end, the Administration should provide for a separate line-item for the 340B program in the 2010 federal budget. In the absence of line-item funding, SNHPA is open to sitting down with Congress, HRSA, and other affected stakeholders to explore the feasibility of alternative funding mechanisms.

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