



# The Monitor

The Inside Source on the Public Health Service 340B Drug Discount Program

January 11, 2007

## **BREAKING NEWS ALERT**

### **Government Proposes New Guidelines Related to Patient Definition and Contract Pharmacies** *Children's Hospital Guidelines Still Pending*

A long-awaited notice proposing clarifications to existing federal guidance on who qualifies as a patient of a 340B covered entity will be published in tomorrow's Federal Register. An additional notice, also due to be published tomorrow, would propose allowing the use of multiple contracted pharmacies by 340B covered entities. A third 340B-related notice – detailing the procedure by which freestanding children's hospitals can qualify for and enroll in the program – is still awaiting publication. *The Monitor* has obtained advance copies of the patient definition and contract pharmacy notices.

The Health Resources and Services Administration (HRSA) issued the patient definition notice in order to “protect the integrity of the program” and to assist covered entities with 340B compliance. If implemented, some stakeholders are concerned that the guidelines would likely increase drug costs for many covered entities, especially those using 340B to fill employee prescriptions or prescriptions written by non-covered-entity physicians. The 340B statute prohibits a covered entity from reselling or otherwise transferring discounted drugs to anyone other than a patient of the entity, but does not define the term “patient.”

The guidelines propose the following:

- To receive 340B-discounted drugs, an individual must be provided health care services from a “provider” employed by or under contract with a covered entity and receive a prescription related to that care. Current guidance specifies that an individual receive services from a healthcare “professional” employed by, under contract with or in “other arrangements” with the entity. HRSA's notice therefore seeks to eliminate the use of 340B drugs for patients receiving care through “other arrangements” and potentially narrows the range of caregivers whose services meet patient definition standards.
- Covered entities must have “ownership, control, maintenance, and possession” of records documenting their health care services, including records documenting the services that “result in the use of, or prescription for, 340B drugs.” Existing guidance specifies that the covered entity is only required to maintain records of an individual's health care.
- For a prescription to qualify under 340B, the covered entity must be primarily responsible for the health care that results in the use of or prescription for 340B drugs. Current guidance places no restrictions on who the prescriber is.
- Facilities at DSHs may participate in the 340B program only if they meet Medicare standards for being “provider-based.” A facility's provider-based status must either be reflected on the hospital's annual Medicare cost report or be demonstrated by submission of a copy of the facility's provider-based attestation. Compliance with Medicare provider-based standards is not required for DSH facilities under current guidance.

---

**The Federal Drug Discount and Compliance Monitor**

1875 Eye Street, NW 12<sup>th</sup> Floor

Washington, DC 20006

Phone: 202-349-4244 Fax: 202-785-1756

[www.drugdiscountmonitor.com](http://www.drugdiscountmonitor.com)

- An individual would not lose his or her patient status if referred for follow-up care to an outside provider as long as the covered entity remains responsible for the service that results in use of 340B drugs. For hospitals, this means that, at a minimum, the individual must receive care from the hospital or a provider-based facility within 12 months after the time of referral. No such limitations on referral care exist under current guidance.

In addition to tightening the definition of patient as described above, HRSA provides several examples of problematic uses of the 340B program including certain case management arrangements, loose affiliations networks, transfer of DSH drugs to facilities that are not provider-based, and employee prescriptions. HRSA grantees and subgrantees would also be forbidden to use 340B for drugs that are not utilized under the scope of the project for which grant funds were received.

The notice also proposes to prohibit Indian tribal organizations from using 340B for non-Indian Health Service beneficiaries without prior approval by the Indian Health Service.

The proposed notice allowing covered entities to contract with multiple pharmacy service sites will also be published tomorrow. The notice would also allow covered entities to serve patients through a combination of in-house and contracted pharmacies, which also is not permitted under current rules absent HRSA approval.

The 340B community is still waiting for HRSA to publish a notice which would implement a provision in the Deficit Reduction Act of 2005 intended to extend 340B pricing to freestanding children's hospitals. 340B stakeholders have been waiting for publication of all three notices for many months, so it is somewhat surprising that only two of the notices are being published.

The public has until March 13, 2007, to submit its comments on the patient definition and multiple contract pharmacy guidelines to HRSA.

More details about these Federal Register notices will appear in *The Monitor*'s January issue. In addition, there will be an in-depth look at these issues at the Third Annual 340B Coalition Winter Conference, which will be held from February 26-28<sup>th</sup> in Salt Lake City, Utah. For more information about the conference, go to [http://www.340bconferences.org/conferences/2007\\_winter/](http://www.340bconferences.org/conferences/2007_winter/).