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Bradford R. Lang  
Public Health Analyst  
Office of Pharmacy Affairs  
Health Resources and Services Administration  
5600 Fishers Lane  
Parklawn Building, Room 10C-03  
Rockville, MD 20857

***Re: Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of “Patient,” (Vo. 72, No. 8), January 12, 2007***

Dear Mr. Lang:

The American Hospital Association (AHA), on behalf of our approximately 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, appreciates the opportunity to comment on the Health Resources and Services Administration’s (HRSA) notice proposing clarifications to the definition of “patient” for whom certain qualified providers can purchase discounted drugs under the 340B program.

The 340B drug discount program provides safety-net hospitals with the ability to purchase drugs at significantly reduced costs. Safety-net hospitals depend on the program to provide pharmacy services to some of their most vulnerable patients. Section 340B of the *Public Health Service Act of 1992* states that it is illegal for covered entities to sell medications purchased under the 340B program to persons who are not considered “patients” of the covered entities. In its January 12 notice, HRSA states that clarifications are necessary to protect the integrity of the 340B program.

However, we urge HRSA to reconsider its proposed changes to the 340B definition of “patient.” We are concerned that the proposed notice, if adopted, would be difficult, if not impossible, for hospitals to implement and would ultimately reduce the ability of disproportionate share hospitals to continue to provide pharmacy services to vulnerable patients.



The proposed patient definition would require a pharmacist to know the prescriber's relationship to the hospital, whether the hospital's medical records document the services that result in the 340B prescription, the ownership status of the medical records, whether there was a proper referral of the patient to a non-hospital prescriber, and whether the patient will return to the hospital for a 12-month follow-up visit. These proposed changes are unrealistic and fail to recognize the work environment of a pharmacist.

Pharmacists rarely would have immediate access to hospital records to determine whether the records would meet these standards. Furthermore, pharmacists do not have the time or the resources to interview the patient or prescriber or to review hospital records in order to identify what services resulted in the prescription.

HRSA further proposes that a non-hospital prescription may only be filled with 340B drugs if the patient returns to the hospital within 12 months of his or her last hospital visit. Hospitals have no control over whether a patient returns for a follow-up appointment. A hospital may schedule an appointment with the patient, but the patient could cancel. Consequently, the hospital has no practical way to ensure that patients return for a follow-up visit.

In addition, HRSA proposes that patients must receive services and prescriptions from a "provider" in order to qualify for the 340B drug program. Many legitimate services are provided by non-physician professionals such as nurses, case managers and social workers. State laws allow these non-physicians to write prescriptions, and it is essential that "providers" include nurses, case managers and social workers.

We welcome the opportunity to work with HRSA to adopt an appropriate definition of "patient" for the 340B program. If you have any questions about our comments, please contact me or Don May, vice president of policy, at (202) 626-2356 or [dmay@aha.org](mailto:dmay@aha.org).

Sincerely,

Rick Pollack  
Executive Vice President