American Hospital Association

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Submitted Electronically

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Mary K. Wakefield, PhD, RN
Administrator
Health Resources and Services Administration
US Department of Health and Human Services
Room 10C-03, Parklawn Building
5600 Fishers Lane Independence Avenue, S.W.
Rockville, MD 20857

RE: HRSA RIN 0906-AA94: Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program (Vol. 76, No. 98), May 20, 2011.

Dear Dr. Wakefield:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) proposed regulation implementing the *Patient Protection and Affordable Care Act* (ACA) provision that excludes orphan drugs for purchase under the 340B drug discount program for four categories of hospitals: free-standing cancer hospitals, critical access hospitals (CAHs), rural referral centers (RRCs) and sole community hospitals (SCHs).

The AHA supports HRSA's interpretation of the ACA's orphan drug exclusion. Safety-net hospitals depend on the 340B program to provide pharmacy services to some of their most vulnerable patients. We strongly supported the ACA's 340B program expansion to CAHs, SCHs, RRCs and free-standing cancer hospitals for outpatient services. However, the ACA excluded discounted orphan drug purchases from the 340B program for these newly eligible hospitals. While we continue to advocate for the repeal of the ACA orphan drug exclusion and further expansion of the 340B program to include inpatient drug purchases, we believe that HRSA's approach to limit the exclusion to when an orphan drug is used to treat a rare condition or disease is consistent with congressional intent to improve access to discounted drugs for these newly eligible safety-net hospitals. The following comments highlight our support for HRSA's implementation of the ACA orphan drug exclusion.

INTERPRETATION OF ORPHAN DRUG EXCLUSION

We support HRSA's interpretation in the proposed rule that limits the orphan drug exclusion from the 340B discounted pricing only to when the orphan drug is used to treat the rare disease or condition for which it received the Food and Drug Administration (FDA) designation as an orphan drug. The proposed rule notes that FDA can award a drug the orphan drug designation for the treatment of a rare disease or condition even though that same drug is also approved for treatment of multiple diseases or conditions not considered rare. HRSA's approach would allow these newly eligible hospitals the ability to purchase orphan drugs at the discounted 340B prices as long as the drugs are used to treat non-orphan disease-related conditions.

We recommend that HRSA exercise some flexibility in allowing hospitals to develop alternative tracking systems to monitor compliance with the orphan drug exclusion. The proposed rule requires that the newly eligible 340B hospitals ensure that orphan drugs purchased are not used for treating rare conditions or diseases, per the orphan drug designation. The hospitals would be required to maintain separate purchasing accounts and auditable records to demonstrate compliance. Currently, the 340B program allows 340B entities to establish an alternate tracking system, subject to HRSA's approval, if the entity cannot track the discounted drugs on a drug-by-drug basis. While we believe that most hospitals would be able to meet these accountability requirements, we recommend that HRSA grant the same flexibility to allow alternate tracking systems to be used in the current 340B program to the orphan drug exclusion accountability requirements.

We support the clarification in the proposed rule that orphan drugs not used to treat rare conditions or diseases <u>are</u> considered covered 340B outpatient drugs, and that pharmaceutical manufacturers cannot put conditions or limitations on the sale of orphan drugs to assure that the eligible 340B hospitals will not violate the orphan drug exclusion. The proposed rule acknowledges the confusion that exists in the marketplace between pharmaceutical manufacturers and the newly eligible 340B hospitals regarding the purchase of orphan drugs. The purpose of the rule is to bring greater clarity to the program's operation by balancing the interests of the 340B entities in achieving savings through discounted drug purchases with pharmaceutical manufacturers' financial incentives to manufacture orphan drugs. Prohibiting manufacturers from placing conditions on the purchase of orphan drugs for non-orphan drug-related conditions will go a long way toward clarifying the orphan drug marketplace for the newly eligible 340B hospitals.

We also support the proposed rule's provision that allows free-standing cancer hospitals to opt out of using the 340B program to purchase orphan drugs and instead purchase the orphan drugs through a Group Purchasing Organization (GPO) without losing their 340B status. Free-standing cancer hospitals are significant purchasers of orphan drugs, and the opt-out provision will allow these hospitals to achieve important savings in drug purchases.

The 340B drug discount program continues to be an important tool for safety-net hospitals to manage drugs costs while serving the needs of vulnerable patients. We support HRSA's narrow interpretation of the ACA orphan drug exclusion and look forward to working with the agency on the future implementation issues for the 340B program.

Thank you for your consideration of our comments. If you have any questions, please contact me or Molly Collins Offner, director of policy development, at (202) 626-2326 or mcollins@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President