



## American Hospital Association®

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### **STATEMENT ON 340B ORPHAN DRUG COURT DECISION**

**RICK POLLACK  
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We are deeply disappointed the U.S. District Court for the District of Columbia late Friday ruled against the Department of Health and Human Services (HHS) in a lawsuit brought by the Pharmaceutical Research and Manufacturers of America (PhRMA). Denying rural and cancer hospitals access to 340B discounts on drugs that will not be used for a rare disease will lead to an inevitable result: the limited resources of those safety net hospitals will be stretched even further and far more patients in the communities served by those hospitals will be adversely affected by reduced patient services and limited access to affordable drugs.

The ruling excludes all drugs with an "orphan" designation from the 340B Drug Pricing Program for rural and cancer hospitals, a program expanded to those hospitals under the Affordable Care Act.

The decision overturns HHS's rule that allowed certain 340B rural and cancer hospitals, such as critical access hospitals, sole community providers, rural referral centers and free-standing cancer hospitals, to purchase orphan drugs through the 340B drug discount program when they did not use the drugs for the treatment of conditions for which the "orphan" drug designation was given.

Last December, the AHA filed a friend-of-the-court brief supporting HHS because we believed and continue to believe that their interpretation in the rule was the only practical approach to preserve access to 340B discounted drugs for the hospitals affected by the 340B Orphan Drug exclusion. The ruling will result in a financial windfall to drug manufacturers for uses of the drug unrelated to the rare disease or condition for which it was given orphan designation, contrary to the language and intent of both the Orphan Drug Act and the ACA.

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