HHS Issues Interpretive Rule Regarding 340B Orphan Drug Pricing

Neil W. Hoffman

On July 21, 2014, the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration issued an interpretive rule regarding 340B discount pricing for orphan drugs under section 340B(e) of the Public Health Service Act. Under this interpretive rule, critical access hospitals, sole community hospitals, rural referral centers, and free-standing cancer hospitals participating in the 340B Federal Drug Pricing Program may purchase orphan drugs at discounted 340B prices if used to treat non-orphan conditions, but not if used to treat the rare conditions for which they were originally designated as orphan drugs. According to HHS, the intent of the interpretive rule is to provide clarity in the market place, maintain savings under the 340B program for these newly eligible providers, and protect financial incentives for manufacturing orphan drugs designated for rare diseases or conditions, as indicated in the Patient Protection and Affordable Care Act.[1]

This interpretive rule comes on the heels of a recent federal court decision, which vacated an HHS final rule implementing this orphan drug exclusion policy.[2] In May, the U.S. District Court for the District of Columbia, in Pharmaceutical Research & Manufacturers of America (PhRMA) v HHS,[3] held that Congress limited HHS' authority to implement rules under the 340B program to (1) establishing an administrative dispute resolution process, (2) the methodology used to calculate ceiling prices, and (3) the imposition of civil monetary sanctions. However, in its decision, the court neither invalidated HHS' statutory interpretation nor precluded the agency's issuance of interpretive guidance, such as, presumably, this interpretive rule.

1 Public Law 111-148.
2 78 Fed. Reg. 44,016 (July 23, 2013).
3 No. 13-01501 (D.D.C. May 23, 2014).

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